

# California Health & Human Services Agency

## Data Exchange Framework Data Sharing Agreement Subcommittee

### Meeting #6

Tuesday, April 26, 2022  
12:00 p.m. to 2:30 pm

# Meeting Participation Options

## *Onsite*

- Members who are onsite are encouraged to log in through their panelist link on Zoom.
  - Members are asked to **keep their laptop's video, microphone, and audio off** 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 ([khousa.vang@chhs.ca.gov](mailto:khousa.vang@chhs.ca.gov)) Khousa 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 Subcommittee staff.
- Participants may also submit comments and questions – as well as requests to receive Data Exchange Framework and Data Sharing Agreement Subcommittee updates – to [CDII@chhs.ca.gov](mailto:CDII@chhs.ca.gov).

# Meeting Participation Options

## *Spoken Comments*

- *Participants and Subcommittee 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 onsite and not using Zoom

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

### If you logged on onsite via Zoom interface

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 do not unmute your laptop. The room’s microphones will broadcast audio

### If you logged on from offsite via Zoom interface

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 phone number 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 Subcommittee 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 Q&A box to ensure all feedback is captured or email their comments to [CDII@chhs.ca.gov](mailto:CDII@chhs.ca.gov).

# Agenda

12:00 PM	<b>Welcome and Roll Call</b> <ul style="list-style-type: none"><li>• <i>John Ohanian, Chief Data Officer, CalHHS</i></li></ul>
12:05 PM	<b>Vision and Meeting Objectives</b> <ul style="list-style-type: none"><li>• <i>John Ohanian</i></li></ul>
12:10 PM	<b>Data Sharing Agreement (DSA)</b> <ul style="list-style-type: none"><li>• <i>Helen Pfister, Partner, Manatt Health</i></li></ul>
1:00 PM	<b><u>Public Comment</u></b>
1:15 PM	<b>Policies and Procedures (P&amp;Ps)</b> <ul style="list-style-type: none"><li>• <i>Jonah Frohlich, Senior Managing Director, Manatt Health</i></li><li>• <i>Dr. Rim Cothren, Independent HIE Consultant to CDII</i></li></ul>
2:25 PM	<b>Next Steps and Closing Remarks</b> <ul style="list-style-type: none"><li>• <i>John Ohanian</i></li></ul>

# Welcome and Roll Call

# Data Sharing Agreement (DSA) Subcommittee

## Members (1 of 2)

Name	Title	Organization
<b>John Ohanian (Chair)</b>	Chief Data Officer	CalHHS
<b>Ashish Atreja</b>	CIO and Chief Digital Health Officer	UC Davis Health
<b>William (Bill) Barcellona</b>	Executive Vice President for Government Affairs	America's Physician Groups (APG)
<b>Jenn Behrens</b>	Chief Information Security Officer	LANES
<b>Michelle (Shelley) Brown</b>	Attorney	Private Practice
<b>Louis Cretaro</b>	Lead County Consultant	County Welfare Directors Association of California
<b>Elaine Ekpo</b>	Attorney	CA Dept. of State Hospitals
<b>Diana Kaempfer-Tong</b>	Attorney	CA Dept. of Public Health
<b>Elizabeth Killingsworth</b>	General Counsel & Chief Privacy Officer	Manifest Medex
<b>Helen Kim</b>	Senior Counsel	Kaiser Permanente
<b>Carrie Kurtural</b>	Attorney & Privacy Officer	CA Dept. of Developmental Services
<b>Steven Lane</b>	Clinical Informatics Director   Family Physician	Sutter Health   Palo Alto Medical Foundation



# Data Sharing Agreement (DSA) Subcommittee

## Members (2 of 2)

Name	Title	Organization
<b>Lisa Matsubara</b>	General Counsel & VP of Policy	Planned Parenthood Affiliates of California
<b>Deven McGraw</b>	Lead, Data Stewardship and Data Sharing, Ciitizen Platform	Invitae
<b>Eric Raffin</b>	Chief Information Officer	San Francisco Department of Health
<b>Morgan Staines</b>	Privacy Officer & Asst. Chief Counsel	CA Dept. of Health Care Services
<b>Ryan Stewart</b>	System VP, Data Interoperability and Compliance	CommonSpirit Health
<b>Lee Tien</b>	Legislative Director and Adams Chair for Internet Rights	Electronic Frontier Foundation
<b>Belinda Waltman</b>	Acting Director, Whole Person Care LA	Los Angeles County Department of Health Services
<b>Terry Wilcox</b>	Director of Health Information Technology/Privacy & Security Officer	Health Center Partners
<b>Sanjay Jain</b>	Sr. Business Analyst	Health Net
<b>Patrick Kurlej</b> <i>(in memoriam)</i>	Director, Electronic Medical Records & Health Information Exchange	Health Net

# Vision and Meeting Objectives

# Vision for Data Exchange in California

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 Objectives



- ① Discuss and provide feedback on the draft **DxF Data Sharing Agreement (DSA)**.
- ② Discuss and provide feedback on the draft **DxF DSA Policies and Procedures (P&Ps)**.

# Data Sharing Agreement (DSA)

# DSA and Policies & 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 1<sup>st</sup>, additional P&Ps will be developed through stakeholder feedback and the DxF governance process.

# Draft DSA Overview and Contents

## DSA Overview

- ❖ Topics previously reviewed by the DSA Subcommittee are highlighted in **blue** and are marked with an asterisk (\*).
- ❖ Many of the DSA topics have undergone redrafting since being reviewed by the DSA Subcommittee.

## 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. Special Compliance Provisions & Applicability of HIPAA\***
- 10. Minimum Necessary\***
11. Individual Access Services
- 12. Cooperation and Non-Discrimination\***
13. Information Blocking
14. Legal Requirements
15. Representation and Warranties
16. Term, Suspension, and Termination
17. Participant Liability
18. Miscellaneous/General Provisions

# Draft DSA and Policies & Procedures

## 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. Special Compliance Provisions & Applicability of HIPAA
10. Minimum Necessary
- 11. Individual Access Services**
12. Cooperation and Non-Discrimination
- 13. Information Blocking**
14. Legal Requirements
15. Representation and Warranties
16. Term, Suspension, and Termination
17. Participant Liability
18. Miscellaneous/General Provisions

## Initial P&Ps (to be released on July 1<sup>st</sup>)

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

## Next Set of P&Ps (released after July 1<sup>st</sup>)\*

1. Monitoring and Auditing
2. Enforcement

## Potential P&Ps (for future development)\*

- 1. Individual Access Services**
- 2. Information Blocking**

## Color Key

- Red = DSA topics that are described in detail in the P&Ps
- Purple = DSA topics for consideration to be moved to P&Ps

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



# Sec 1. Parties; Sec 2. Purpose and Intent

## SECTION 1: PARTIES

This Single Data Sharing Agreement is made between the California Health and Human Services Agency and Participants who are required to or elect to exchange Health and Social Services Information within the State of California in accordance with this Agreement.

## SECTION 2: PURPOSE AND INTENT

- (a) California Health and Safety Code § 130290 was enacted in 2021 and establishes the creation of the California Health and Human Services Data Exchange Framework and requires certain data sharing among entities as set forth in California Health and Safety Code § 130290(f) by January 31, 2024. The framework includes this single data sharing agreement and a set of common policies and procedures.
- (b) This Agreement is intended to facilitate data exchange between the Participants in compliance with all applicable federal, state, and local laws, regulations, and policies. This Agreement 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.
- (c) This Agreement is not intended nor designed to: (i) mandate or require a specific technology; (ii) create a single entity that exchanges Health and Social Services Information; or (iii) create a single repository of data.

## Key Considerations

1. **Definition of “Health and Social Services Information”:** “Any and all information received, stored, processed, generated, used, transferred, disclosed, made accessible, or shared pursuant to this Agreement, 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 PHI; and (c) information related to the provision of social services. Health and Social Services Information may include PHI, 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 4. Use of Health & Social Services Information

## Provisions

**(a) Required and Permitted Purposes.** The purposes for which the Participants shall or may acquire, access, use, and disclose Health and Social Services Information pursuant to this Agreement shall be set forth in the Policies and Procedures.

**(b) Prohibition on Use for a Participant's Direct or Indirect Financial Benefit.** As described in more detail in the Policies and Procedures, Participants shall not be permitted to acquire, access, use, or disclose Health and Social Services Information for their own indirect or direct financial benefit.

## Key Considerations

1. **Definition of "Agreement":** "This Data Sharing Agreement, the Policies and Procedures and the Specifications."

# Sec 5. Policies & Procedures and Specifications

## Provisions

- (a) Compliance with Terms of this Agreement.** Participants shall at all times abide by this Agreement, including the Policies and Procedures and Specifications.
- i. Policies and Procedures and any future updates to them are hereby incorporated by reference into this Agreement. Policies and Procedures are intended to be flexible to address changing needs and may be modified from time to time through the process outlined in the Policies and Procedures without a need to modify or re-execute this Agreement.
  - ii. Specifications and any future updates to them are hereby incorporated by reference into this Agreement. Specifications are intended to be flexible to address changing standards and may be modified from time to time through the process outlined in the Policies and Procedures without a need to modify or re execute this Agreement.

## Key Considerations

- 1. The P&Ps and the Specifications are incorporated in the DSA.**
- 2. The P&Ps and the Specifications may be modified over time.**

# Sec 6. Authorizations

## Provisions

- a) Except for disclosures which may be made without an Authorization under Applicable Law, Participants shall not disclose PHI or PII to another Participant unless a legally valid Authorization has been obtained.
- b) Participants may accept another Participant's representations that a legally valid Authorization has been obtained. A Participant who provides assurances that an Authorization is legally valid shall indemnify and hold harmless a Participant who reasonably relied upon the assurances, unless the Participant is prohibited from providing such indemnification under Applicable Law.
- c) Participants who have received an Authorization shall:
  - i. Be responsible for ensuring the Authorization complies with all Applicable Law; and
  - ii. Be responsible for maintaining documentation as required under Applicable Law and make such documentation available to other Participants in the event of a complaint, litigation, or other dispute. Participants may rely on documentation for a legally valid release of information submitted by third parties who are not Participants.
- d) Before disclosing PHI or PII, a Participant may request a copy of an Authorization and, within a reasonable time of receiving the Authorization, evaluate the Authorization to ensure it is legally valid. Once a Participant has determined the Authorization is legally valid, it shall disclose PHI or PII consistent with the Authorization and with the request for PHI or PII. A Participant who chooses not to provide assurances that an Authorization is legally valid shall not be liable to the other Participant that acts upon the Authorization for the lack of legal validity of the Authorization.
- e) If a Participant has determined that an Authorization is not legally valid or has been revoked, the Participant shall not disclose PHI or PII but shall inform the Participant requesting PHI or PII that the Authorization is legally insufficient and explain why. In no case shall a Participant disclose PHI or PII if an Authorization has been revoked or is legally insufficient.

# Sec 7. Requirement to Exchange Health & Social Services Information

## Provisions

“Each Participant shall engage in the exchange of Health and Social Services Information as set forth in the Policies and Procedures either through execution of an agreement with an entity that provides data exchange or through use of their own technology.”

## Key Considerations

1. The “Requirement to Exchange Health and Social Services Information” P&P includes details on:
  - Duty to respond
  - The intent for DxF to be technology agnostic
  - Definitions of permitted and required purposes

# Sec 8. Privacy and Security

## Provisions

- a) **General.** Each Participant shall at all times fully comply with all Applicable Law relating to this Agreement and the use of Health and Social Services Information.

# Sec 8. Privacy and Security.... continued

## Provisions

- b) **Safeguards.** Each Participant shall be responsible for maintaining a secure environment that supports the exchange of Health and Social Services Information pursuant to this Agreement. Participants shall use appropriate safeguards to prevent unauthorized use or disclosure of Health and Social Services Information in a manner consistent with HIPAA Regulations, including implementing appropriate administrative, physical, and technical safeguards that protect the confidentiality, integrity, and availability of that Health and Social Services Information. Participants shall also be required to comply with any Specifications or Policies and Procedures that define requirements and expectations for Participants with respect to enterprise privacy and security. Each Participant represents and warrants that it shall comply with the applicable safeguards as follows:.
- i. A Participant with access to PHI or PII shall use safeguards identified in the HIPAA Security Rule, 45 C.F.R. Part 160 and Part 164, Subparts A and C, as safeguards, standards, “required” implementation specifications, and “addressable” implementation specifications to the extent that the “addressable” implementation specifications are reasonable and appropriate in the Participant’s environment. If an “addressable” implementation specification is not reasonable and appropriate in the Participant’s environment, then the Participant must document why it would not be reasonable and appropriate to implement the implementation specification and implement an equivalent alternative measure if reasonable and appropriate;
  - ii. Governmental Participants shall take all appropriate safeguards required by Applicable Law or policies issued by government entities related to information privacy and security, including to the extent applicable, HIPAA; or
  - iii. Social Services Organizations shall take all appropriate safeguards required by Applicable Law, policies set forth by applicable federal or state government entities (such as but not limited to regulatory agency guidance), or required by a legally enforceable agreement with a government entity, Governmental Participant, or other Social Services Organization.

## Key Considerations

1. **Definition of “Social Services Organization”:** “an entity that is legally authorized to perform or provide Social Services to individuals. Social Services Organizations can include but are not limited to government entities, community-based organizations, non-profits, and private entities.”

# Sec 8. Privacy and Security.... continued

## Provisions

- c) ***Policies and Procedures and Training.*** Each Participant shall, pursuant to this Agreement, Applicable Law, or applicable federal and state guidance, have written privacy and security policies relating to the use and disclosure of PHI or PII that are consistent with and satisfy the requirements set forth in the HIPAA Regulations. Before granting access to PHI or PII, each Participant shall train staff, contractors, agents, employees, and workforce members, as defined under the HIPAA Regulations, who will have access to PHI or PII under this Agreement. Each Participant shall also provide refresher training consistent with each Participant's internal privacy and security policies but no less than annually.
- e) ***Malicious Software.*** Each Participant shall ensure that it employs security controls that meet applicable industry or Federal standards so that Health and Social Services Information exchanged pursuant to this Agreement and any method of exchanging such information will not introduce any viruses, worms, unauthorized cookies, trojans, malicious software, "malware," or other program, routine, subroutine, or data designed to disrupt the proper operation of a System or any part thereof or any hardware or software used by a Participant in connection therewith, or which, upon the occurrence of a certain event, the passage of time, or the taking of or failure to take any action, will cause a System or any part thereof or any hardware, software or data used by a Participant in connection therewith, to be improperly accessed, destroyed, damaged, or otherwise made inoperable. In the absence of applicable legal or industry standards, each Participant shall use all commercially reasonable efforts to comply with the requirements of this Section.
- f) ***Breach Notification.*** Participants shall comply with the Breach Notification requirements as set forth in the Policies and Procedures.

## Key Considerations

1. **Definition of "System":**  
"Software, portal, platform, or other electronic medium controlled by a Participant through which the Participant conducts Health and Social Services Information exchange related activities. For purposes of this definition, it shall not matter whether the Participant controls the software, portal, platform, or medium through ownership, lease, license, or otherwise."



# Sec 9. Special Compliance Provisions & Applicability of HIPAA

## Provisions

(a) To support the privacy, confidentiality, and security of PHI, each Participant hereby represents and warrants:

- i. If the Participant is a Covered Entity or a covered component of a Hybrid Entity, the Participant does, and at all times shall, comply with the HIPAA Regulations to the extent applicable and with Applicable Law.
- ii. If the Participant is a Business Associate, the Participant does, and at all times shall, comply with the provisions of its Business Associate Agreements (or for governmental entities relying upon 45 C.F.R. part 164.504(e)(3)(i)(A), its Memoranda of Understanding) and Applicable Law.
- iii. If the Participant is a Governmental Participant, the Participant does, and at all times shall, comply with Applicable Law.
- iv. If the Participant is a Social Services Organization, the Participant does, and at all times shall, comply with Applicable Law, any applicable contract, and policies set forth by applicable federal or state government entities.
- v. Except as otherwise set forth in this Agreement, if the Participant is neither a Covered Entity, a Business Associate, covered component of a Hybrid Entity, Social Services Organization, nor a Governmental Participant, the Participant shall, as a contractual standard, at all times, at a minimum, comply with the provisions of the HIPAA Regulations at 45 CFR Part 164 as if it were acting in the capacity of a Covered Entity or such other standards as may be adopted by the Governance Entity.

(b) Each Participant acknowledges Participants do not become a Business Associate of another Participant by virtue of signing this Agreement or exchanging PHI pursuant to this Agreement.

## Key Considerations

- 1. Establishes HIPAA as a floor for all entities in 9(a)(v).**
- 2. Definition of “Hybrid Entity”:** “The same meaning as set forth in 45 C.F.R. § 164.103.”

# Sec 10. Minimum Necessary

## Provisions

- (a) Any use or disclosure of PHI or PII pursuant to this Agreement will be limited to the minimum PHI or PII necessary to achieve the purpose for which the information is shared, except where limiting such use or disclosure to the minimum necessary is not feasible and is not required under the HIPAA Regulations.
- (b) Participants shall not request more PHI or PII than necessary to achieve the purpose of the request for PHI or PII.
- (c) This Section shall not apply in the following circumstances:
  - i. A disclosure of PHI to or request by a Health Care Provider for Treatment;
  - ii. A disclosure to an Individual User who is the subject of the information;
  - iii. A disclosure pursuant to an Individual User's Authorization; or
  - iv. Disclosures that are required by law as described in 45 C.F.R. part 164.512(a) or Applicable Law.

# Sec 11. Individual Access Services

## Provisions

**(a) Individual User Access.** An Individual User or Personal Representative may assert their right of Individual Access Services with respect to a Participant if the Participant has a Direct Relationship with the Individual User. The Participant may require the Individual User or Personal Representative to assert their right to access their PHI or PII in writing, which may be done electronically, and, to the extent permitted by HIPAA, may require such Individual User or Personal Representative to use the Participant's own supplied form. Each Participant shall provide the Individual User or 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.

**(b) Individual Use or Disclosure of PHI or PII.** Individuals shall have the right to Use or Disclose their own PHI or PII without any limitations.

**(c) Authentication.** Prior to initiating Individual Access Services, the Participant shall be required to verify the identity of the Individual User or Personal Representative using standards and methods consistent with 45 CFR § 164.514(h).

**(d) No Fees for Individual Access Services.** A Participant may not charge another Participant any amount for PHI or PII exchanged in furtherance of this Section.

## Key Considerations

**1. Definition of “Personal Representative”:** A person that, under Applicable Law, has authority to act on behalf of an individual as set forth in 45 CFR § 164.502(g).”

# Sec 11. Individual Access Services...continued

## Provisions

**(e) Processing of Individual Access Services Requests.** Participants shall process Individual User or Personal Representative requests for Individual Access Services as follows:

- i. Each Participant that receives a request for Individual Access Services from an Individual User or Personal Representative with whom it has a Direct Relationship shall provide such Individual User or Personal Representative with Individual Access Services with respect to their PHI or PII regardless of whether the Participant is a Covered Entity or Business Associate; provided, however, that if the Individual User wants the PHI or PII to go to a third party, the Individual User has satisfied the conditions at 45 C.F.R. part 164.524(c)(3)(ii) as it applies to PHI or PII;
- ii. When the Participant is acting as a Business Associate and the request for Individual Access Services is received by a Covered Entity Participant that directs the Business Associate Participant to satisfy the request, then the Business Associate Participant may respond to a request for Individual Access Services if permitted or required by the terms of the applicable Business Associate Agreement or otherwise required by Applicable Law; or
- iii. With respect to a Participant query for Individual Access Services, the response shall be provided as required by these terms and conditions regardless of whether it was prompted by (a) the Individual User; or (b) a Participant, who provides Individual Access Services and has been selected by the Individual User who is requesting PHI or PII for Individual Access Services.

# Sec 12. Cooperation & Non-Discrimination

## Provisions

(a) Each Participant understands and acknowledges that numerous activities with respect to this Agreement shall likely involve another Participant's employees, agents, third party contractors, vendors, or consultants. To the extent not legally prohibited, each Participant shall:

- i. Cooperate fully with the Governance Entity, each other Participant, and any such third parties with respect to such activities as they relate to this Agreement;
- ii. Provide such information to the Governance Entity, each other Participant, or such third parties as they may reasonably request for purposes of performing activities related to this Agreement;
- iii. Actively engage in the bilateral or multilateral exchange of information with other Participants as both a Submitter and Recipient of information to the extent permitted or required under this Agreement and Applicable Law;
- iv. 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 this Agreement;
- v. Provide such reasonable assistance as may be requested by the Governance Entity when performing activities as they relate to this Agreement; and
- vi. 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 or protecting a Participant's Confidential Participant Information, provide information and assistance to the Governance Entity or other Participants in the investigation of Breaches and Disputes. In no case shall a Participant be required to disclose PHI or PII in violation of Applicable Law.

# Sec 12. Cooperation & Non-Discrimination...continued

## Provisions

**(b)** In seeking another Participant's cooperation, each Participant shall make all reasonable efforts to accommodate the other Participant's schedules and reasonable operational concerns. A Participant shall promptly report, in writing, to any other Participant and the Governance Entity, any problems or issues that arise in working with the other Participant's employees, agents, or subcontractors that threaten to delay or otherwise adversely impact a Participant's ability to fulfill its responsibilities under this Agreement. This writing shall set forth in detail and with clarity the problems that the Participant has identified.

**(c) *Prohibition on Exclusivity.*** A Participant may not require exclusivity or otherwise prohibit (or attempt to prohibit) any other Participant, entity, or individual, from joining or exchanging Health and Social Services Information under this Agreement.

**(d) *No Discriminatory Limits on Exchange of Health and Social Services Information.*** A Participant shall not unfairly or unreasonably limit exchange or interoperability with any other Participant or Individual User such as by means of burdensome testing requirements that are applied in a discriminatory manner or other means that limit the ability of a Participant to send or receive Health and Social Services Information with another Participant or Individual User or slows down the rate at which such Health and Social Services Information is sent or received if such limitation or slower rate would have an anti-competitive effect.

# Sec 13. Information Blocking

## Provisions

(a) Participants shall not engage in any practice that constitutes information blocking defined under 42 U.S. Code § 300jj–52, its implementing regulations and as set forth in the Policies and Procedures, if any.

## Key Considerations

1. **As drafted, this provision would expand the entities required to comply with these rules.**

# Sec 14. Legal Requirements

## Provisions

**(a) *Monitoring and Auditing.*** The Governance Entity, acting through its agents and independent contractors, in order to confirm compliance with this Agreement, shall have the right, but not the obligation, to monitor and audit Participants' compliance with their obligations under this Agreement as set forth in the Policies and Procedures. Unless prohibited by Applicable Law, Participants shall cooperate with the Governance Entity in these monitoring and auditing activities and shall provide, upon the reasonable request of the Governance Entity, complete and accurate information in the furtherance of its monitoring and auditing activities. To the extent that any information provided by Participants to the Governance Entity in connection with such monitoring and auditing activities constitutes Confidential Participant Information, the Governance Entity shall hold such information in confidence and shall not redisclose such information to any person or entity except as required by Applicable Law.

## Key Considerations

- 1. Monitoring and auditing details to be provided in a forthcoming P&P.**



# Sec 15. Representations & Warranties

## Provisions

Each Participant hereby represents and warrants the following:

- (a) Execution of the Agreement.** Each Participant affirms that it has full power and authority to enter into and perform this Agreement and has taken whatever measures necessary to obtain all required approvals or consents in order for it to execute this Agreement. The representatives signing this Agreement on behalf of the Participants affirm that they have been properly authorized and empowered to enter into this Agreement on behalf of the Participant.
- (b) Compliance with this Agreement.** Except to the extent prohibited by Applicable Law, each Participant shall comply fully with all provisions of this Agreement. To the extent that a Participant delegates its duties under this Agreement to a third party (by contract or otherwise) and such third party will have access to Health and Social Services Information, that delegation shall be in writing and require the third party, prior to exchanging Health and Social Services Information with any Participants, to agree to the same restrictions and conditions that apply through this Agreement to a Participant. If a Governmental Participant determines, after reasonable diligence, that any action or inaction relative to an obligation, including conformance to changes in the Specifications or Policies and Procedures will cause it to violate Applicable Law, the Governmental Participant may terminate this Agreement immediately upon sending written notice to the Governance Entity.
- (c) Compliance with Specifications, Policies and Procedures.** Each Participant affirms that it shall fully comply with any and all Specifications and Policies and Procedures.

# Sec 15. Representations & Warranties... Continued

## Provisions

- d) Accuracy of Health and Social Services Information.** When acting as a Submitter, each Participant hereby represents that at the time of transmission, the Health and Social Services Information it provides is (a) an accurate representation of the data contained in, or available through, its System, (b) sent from a System that employs security controls that meet industry standards so that the Health and Social Services Information being transmitted is intended to be free from malicious software in accordance with Section 8, and (d) provided in a timely manner and in accordance with the Policies and Procedures. Other than those representations elsewhere in this Agreement, the Submitter makes no other representation, express or implied, about the Health and Social Services Information.
- e) Express Warranty of Authority to Exchange Health and Social Services Information.** To the extent each Participant discloses Health and Social Services Information to another Participant, the Participant represents and warrants that it has sufficient authority to disclose such Health and Social Services Information.
- f) Third Party Technology.** All Participants acknowledge that other Participants use technology solutions, applications, interfaces, software, platforms, clearinghouses and other IT resources to support exchange of Health and Social Services Information that may be provided by third parties (“**Third Party Technology**”). Each Participant shall have agreements in place that require Third Party Technology vendors (i) to provide reliable, stable and secure services to the Participant and (ii) to adhere to the same privacy and security standards applicable to the Participant pursuant to this Agreement. However, all Participants acknowledge that Third Party Technology may be non-functional or not available at times and that this could prevent a Participant from transmitting Health and Social Services Information. Participants do not make any representations or warranties as to their Third Party Technology.

# Sec 16. Term, Suspension and Termination

## Provisions

- (a) Term.** This Agreement shall commence on the Effective Date and shall continue until terminated in accordance with this Section or the Policies and Procedures.
- (b) Termination by a Participant.** A Participant who is not legally required to sign this Agreement by California Health and Safety Code § 130290 may terminate this Agreement, with or without cause, by giving the Governance Entity at least ten (10) business days prior written notice.
- (c) Effect of Termination.** Upon any termination of this Agreement for any reason, the terminated party shall cease to be a Participant and thereupon and thereafter that party shall have no rights under this Agreement to exchange data with other Participants. In the event that any Participant(s) is terminated, this Agreement will remain in full force and effect with respect to all other Participants. Termination of this Agreement shall not affect any rights or obligations which by their terms should survive termination or expiration.
- (d) Enforcement Action.** The Participants hereby grant to the Governance Entity the power to enforce any portion of this Agreement through measures set forth in the Policies and Procedures. Such measures may include, but are not limited to, suspension or termination of a Participant's right to exchange Health and Social Services Information.

# Sec 17. Participant Liability

## Provisions

Each Participant shall be responsible for its acts and omissions and not for the acts or omissions of any other Participant. In circumstances involving harm to other Participants caused by the acts or omissions of individuals who transmit Health and Social Services Information through the Participant or by use of any password, identifier, or log-on received or obtained directly or indirectly, lawfully or unlawfully, from the Participant, each Participant shall be responsible for such harm to the extent that the harm was caused by the Participant's breach of the Agreement or its negligent conduct for which there is a civil remedy under Applicable Law. Notwithstanding any provision in this Agreement 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 18. Miscellaneous/General Provisions

## Provisions

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

# Public Comment Period

# Policies & Procedures (P&Ps)

# Policies & Procedures

## Initial P&Ps (to be released on July 1<sup>st</sup>)

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



# (1) Amendment of DSA

## Policy

The Governance Entity shall follow the process set forth in this policy in order to amend the DSA. An amendment to the DSA shall be effective only if implemented as provided in this policy.

## Key Procedures

1. The Governance Entity shall maintain 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, in a publicly accessible location.
2. Any member of the Governance Entity, Participant or any other stakeholder that the Governance Entity deems appropriate may submit in writing to the Governance Entity a request for an amendment to the DSA.
3. The Governance Entity shall define criteria for which requests for proposed amendments merit additional consideration.
4. If a request for a proposed amendment satisfies the criteria established by the Governance Entity, the Governance Entity will forward such requests to legal counsel for an initial legal review.
5. Following initial legal review, a task force established by the Governance Entity shall, in consultation with local partners and a stakeholder advisory group appointed by the Secretary of California Health and Human Services, determine how to address the request.
6. Prior to approving any amendments to the DSA, the task force shall solicit and consider comments from the Participants on the new, amended, repealed or replaced provisions of the DSA.
7. Following the task force's approval of the amendment to the DSA, the Participants shall be given thirty (30) calendar days to review the approved amendment and register an objection.
8. If the task group's recommendation is to amend the DSA and the Governance Entity approves such a recommendation, the Governance Entity will circulate the amendment to all of the Participants for signature at least thirty (30) calendar days prior to the effective date of the amendment.

## (2) Amendment of Policies and Procedures

### Policy

As may become necessary for the proper functioning of the Data Exchange Framework, the Governance Entity may establish a new Policy, or it may amend, repeal, and/or replace any existing Policies, consistent with this policy and the Data Exchange Framework Guiding Principles.

### Key Procedures

1. Any Participant or other stakeholder 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.
2. 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.
3. Prior to approving any new, amended, repealed or replaced Policy, the Governance Entity shall solicit and consider comments from the Participants on the new, amended, repealed or replaced Policy.
4. Following the Governance Entity's approval of the new, amended, repealed or replaced Policy, the Participants shall be given thirty (30) calendar days to review the approved Policy and provide written comments to the Governance Entity.
5. If the Governance Entity receives no comments from Participants during the thirty (30) calendar day objection period, the new, amended, repealed or replaced Policy shall go into effect.
6. If the Governance Entity receives comments from Participants during such thirty (30) calendar day 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.

# (3) Data Elements to be Exchanged

## Policy

Participants shall make available or exchange, at a minimum, data as defined in this policy.

## Key Procedures

1. Participants shall make available or exchange, at a minimum, data as defined in the subparagraphs below.
  - a. **Health Care Providers:** 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 and held by the entity.
  - b. **County health facilities and public health agencies:** the same data required of Health Care Providers, as allowed by Applicable Law.
  - c. **Health Plans:** data required to be shared under the Centers for Medicare and Medicaid Services Interoperability and Patient Access regulations for public programs
  - d. **Intermediaries:** the same data that is required to be shared by the organizations for whom the intermediary is facilitating exchange

# (3) Data Elements to be Exchanged...continued

## Key Procedures

2. Participants shall use standardized data element formats, terminologies, and code sets identified in the most recent published (in non-draft form) **United States Core Data for Interoperability (USCDI)**. For data elements not included in USCDI, Participants shall use standardized data element formats, terminologies, and code sets identified in applicable nationally recognized standards.
3. Participants shall use nationally recognized data standard formats in the exchange of Health and Social Services Information, which may include one of:
  - a. HL7 Messaging Standard Version 2.5.1 or greater
  - b. HL7 Clinical Document Architecture (CDA®) Release 2, HL7 Companion Guide to Consolidated Clinical Document Architecture (C-CDA®) 2.1 preferred if applicable
  - c. HL7 Fast Health Interoperability Resources (FHIR®) Release 4.0.1, US Core Implementation Guide 4.0.0 STU4 or greater preferred.

# (4) Breach Notification

## Policy

- “Breach” shall mean the unauthorized acquisition, access, disclosure, or use of Health and Social Services Information.
- 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 in accordance with the procedures herein.

## Key Procedures

1. After determining that a Breach has occurred, a Participant shall provide notification as soon as reasonably practicable, but no later than (i) two (2) calendar days to the Governance Entity and affected Participants, and (ii) ten (10) calendar days to other affected individuals and/or entities.
2. Notwithstanding the above, Participants agree that within twenty-four (24) hours following the discovery of a Breach that may involve a Participant that is a Governmental Participant, Participants shall provide notification to all Governmental Participants that are likely impacted by the Breach in accordance with the procedures and contacts provided by such Governmental Participant.

# (5) Permitted, Required, and Prohibited Purposes

## Policy

Participants are required to exchange Health and Social Services Information or provide access to Health and Social Services Information for the Required Purposes set forth in this policy. Participants may exchange Health and Social Services Information or provide access to Health and Social Services Information for the Permitted Purposes set forth in this policy.

Nothing in this policy is intended to restrict a Participant from having different arrangements outside of the DSA provided that the Participant can still comply with the DSA.

## Key Procedures

### 1. Required Purposes

a. Subject to the provisions of the DSA and the Policies and Procedures, Participants are required to exchange and/or provide access to Health and Social Services Information pursuant to the Data Exchange Framework for **Treatment, Payment, Public Health Activities and the following types of Health Care Operations.**

1. Quality Assessment and Improvement activities as described in subsection (1) of the definition of health care operations set forth at 45 C.F.R. § 164.501.
2. Population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives as set forth at 45 C.F.R. § 164.501.

### 2. Permitted Purposes

a. Subject to the provisions of the DSA and the Policies and Procedures, Participants are permitted to exchange or provide access to Health and Social Services Information **for any other purpose**, provided appropriate Authorizations are made, if necessary, and the disclosure or use of Health and Social Services Information is permissible under Applicable Law.

# (5) Permitted and Required Purposes...continued

## Key Procedures

### 3. Prohibited Purposes

- a. Unless permitted by Applicable Law or the DSA, Participants shall not, for their own indirect or direct financial benefit, re-use, re-disclose, aggregate, de-identify, re-identify, or engage in the Sale of Health and Social Services Information\* received through the DSA 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:
  1. The Participant is a Business Associate 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. This shall not include the Sale of Health and Social Services Information;
  2. The Participant is performing Individual Access Services at the direction of an Individual User or Personal Representative; or
  3. 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.

\* The “Sale of Health and Social Services Information” is defined as the disclosure of Health and Social Services Information in return for direct or indirect remuneration from or behalf of the recipient of the Health and Social Services Information. Sale of Health and Social Services Information shall not include the disclosure of Health and Social Services Information for the activities set forth in 45 CFR § 164.502(a)(5)(ii)(B)(2).

# (6) Requirement to Exchange Health & Social Services Information

## Policy

California Health and Safety Code § 130290 was enacted in 2021 and establishes the creation of the California Health and Human Services Data Exchange Framework (“Data Exchange Framework”), which requires certain data sharing among Participants. All Participants shall exchange Health and Social Services Information in accordance with this policy.

## Key Procedures

1. Duty to Respond
  - a. All Participants that request Health and Social Services Information for Permitted Purposes or Required Purposes shall have a corresponding reciprocal duty to respond to requests for Health and Social Services Information for these purposes. A Participant shall fulfill its duty to respond by either (i) providing the requested Health and Social Services Information, or (ii) responding with a standardized response that indicates the Health and Social Services Information is not available or cannot be exchanged.
2. Technology Agnostic
  - a. The Data Exchange Framework is intended to be technology agnostic, meaning that no particular technology or method to exchange data is preferred.
  - b. Each Participant agrees to exchange Health and Social Services Information in accordance with the Data Exchange Framework to the extent the Participant is technologically ready and able and as set forth in the Policies and Procedures.



# (6) Requirement to Exchange Health & Social Services Information

...continued

## Key Procedures

- c. Starting January 31, 2024, the following Participants shall be considered technologically ready and able and shall exchange information under the Data Exchange Framework and any other information sharing agreements they are parties to:
  - 1) Healthcare organizations as set forth in California Health and Safety Code § 130290(f), except for those set forth in section 130290(b)(2); and
  - 2) health information networks, health information organizations, health information service providers, or electronic health records technology providers.
  
- d. The following Participants may access Health and Social Services Information under the Data Exchange Framework but are not required to disclose information until they are technologically able and ready:
  - 1) Any healthcare provider, organization, group, facility, hospital, clinic, laboratory, health care service plans and health insurers, disability insurer not set forth in Section (2)(c) above;
  - 2) Governmental Participants; and
  - 3) Social Services Organizations.
  
- e. 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 Data Exchange Framework.

# Next Steps and Closing Remarks

# DxF, DSA, and P&Ps Milestones

Status	DSA SC Meeting	Activity / Milestone
✓	1	Convene DSA Subcommittee; discuss subcommittee purpose & existing data sharing agreements
✓	2	Discuss key considerations and threshold questions for DxF DSA development
✓	3	Preview draft DxF DSA outline; discuss draft language for first set of topics
✓	4	Discuss draft language for second set of topics
✓	5	Discuss digital identity strategy and draft language for third set of DxF DSA topics
✓	6	Discuss proposed drafts for public comment of DxF DSA and initial set of P&Ps
May 11*	NA	Share <b>full drafts of the DxF, DxF DSA, and initial set of P&amp;Ps</b> with the Advisory Group
May 18*	NA	Release <b>full drafts of the DxF, DxF DSA, and initial set of P&amp;Ps</b> for public comment
Jun 1*	NA	Public comments due for the <b>draft DxF, DxF DSA, and initial set of P&amp;Ps</b>
Jul 1	NA	Release of the DxF, DxF DSA, and initial set of P&Ps

\* Tentative dates

# Next Steps

## CalHHS will...

- Summarize the meeting and circulate notes for review
- Continue to develop and revise draft DxF DSA and P&Ps
- Transmit to you (and post on the [DxF website](#)) a template for your comments on the draft DxF DSA and P&Ps

## Members will...

- Provide feedback on the draft DSA and P&Ps (by Friday, Apr 29<sup>th</sup>)
- Review meeting notes and provide feedback to CalHHS staff