

Connecting for Better Health

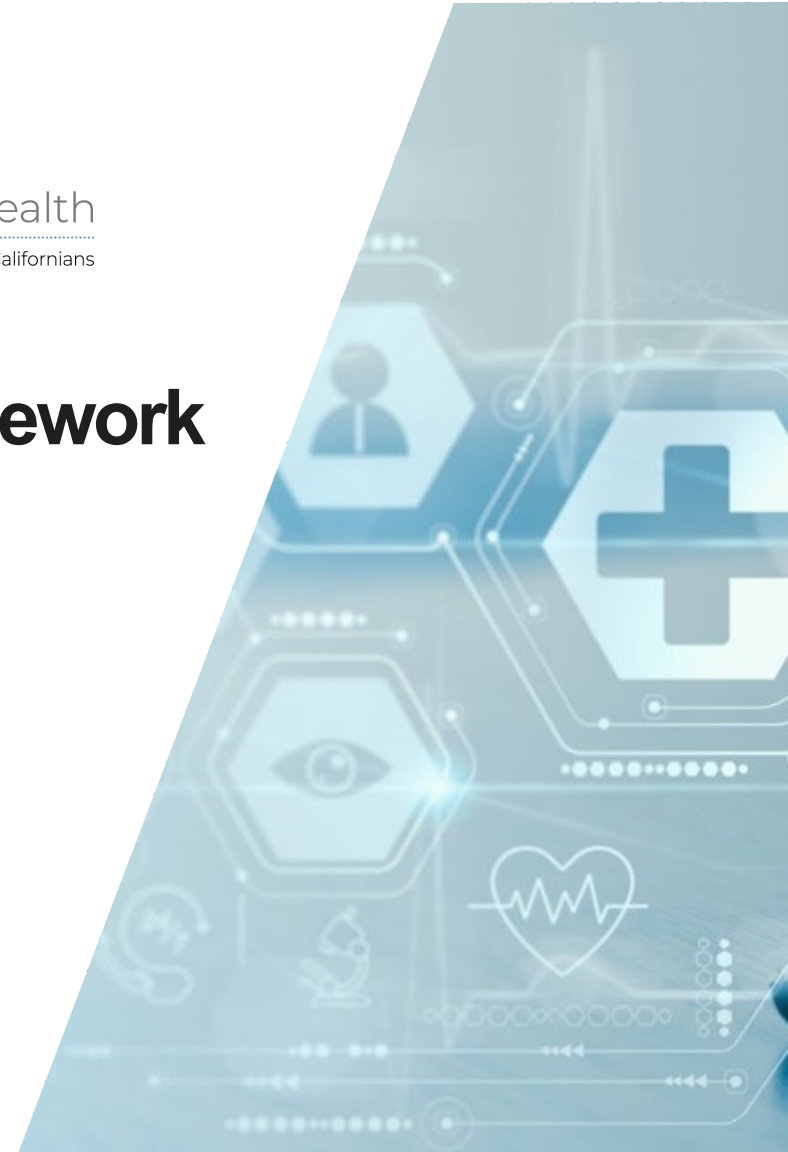
Advancing data sharing to improve the health of all Californians

California's Data Exchange Framework and the Data Sharing Agreement

Multi- Association DxP Education Office Hours

July 5, 2023

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Agenda



- DxF Overview
- DxF Implementation Specifics
 - California Information Blocking Prohibitions
 - Comparison to federal Info Blocking rule
- Questions and Responses

The Vision for Data Exchange in California

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

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



Source: CDII Information is Power Webinar, March 23, 2022

About the Data Exchange Framework

- **Background:** [Assembly Bill 133](#) (codified at [Health and Safety Code § 130290](#)) required the California Health and Human Services Agency (CalHHS), in consultation with stakeholders and local partners, to establish a Data Exchange Framework (DxF) to **govern and require the exchange of health information** among health care entities and government agencies in California.
- **Purpose:** the purpose of the DxF is to promote secure electronic health data exchange among health care providers, consumers of health care and others.

About the Data Exchange Framework

What the DxF is

- The DxF provides the **rules of the road** to bring existing standalone health systems, providers, and social services together to seamlessly provide better care and outcomes for all Californians.
- The DxF is a **technology-agnostic** collection of organizations that are required to share health information using national standards and a common set of policies in order to improve the health outcomes of the individuals they serve.
- The DxF includes a **strategy for unique, secure digital identities** capable of supporting master patient indices to be implemented by both private and public organizations in California. **Signing the DSA is the first step of the DxF implementation process.**

What the DxF *isn't*

- The DxF **is not a technology system or a single repository of data.**

What is the Data Sharing Agreement?

In July 2022, CalHHS/CDII published the DxF Data Sharing Agreement (DSA) and its initial Policies & Procedures (P&Ps), informed by a year-long stakeholder engagement process.

DxF Data Sharing Agreement (DSA)

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

- ✓ *Streamlined document that focuses on the key legal requirements*

Policies & Procedures (P&Ps)

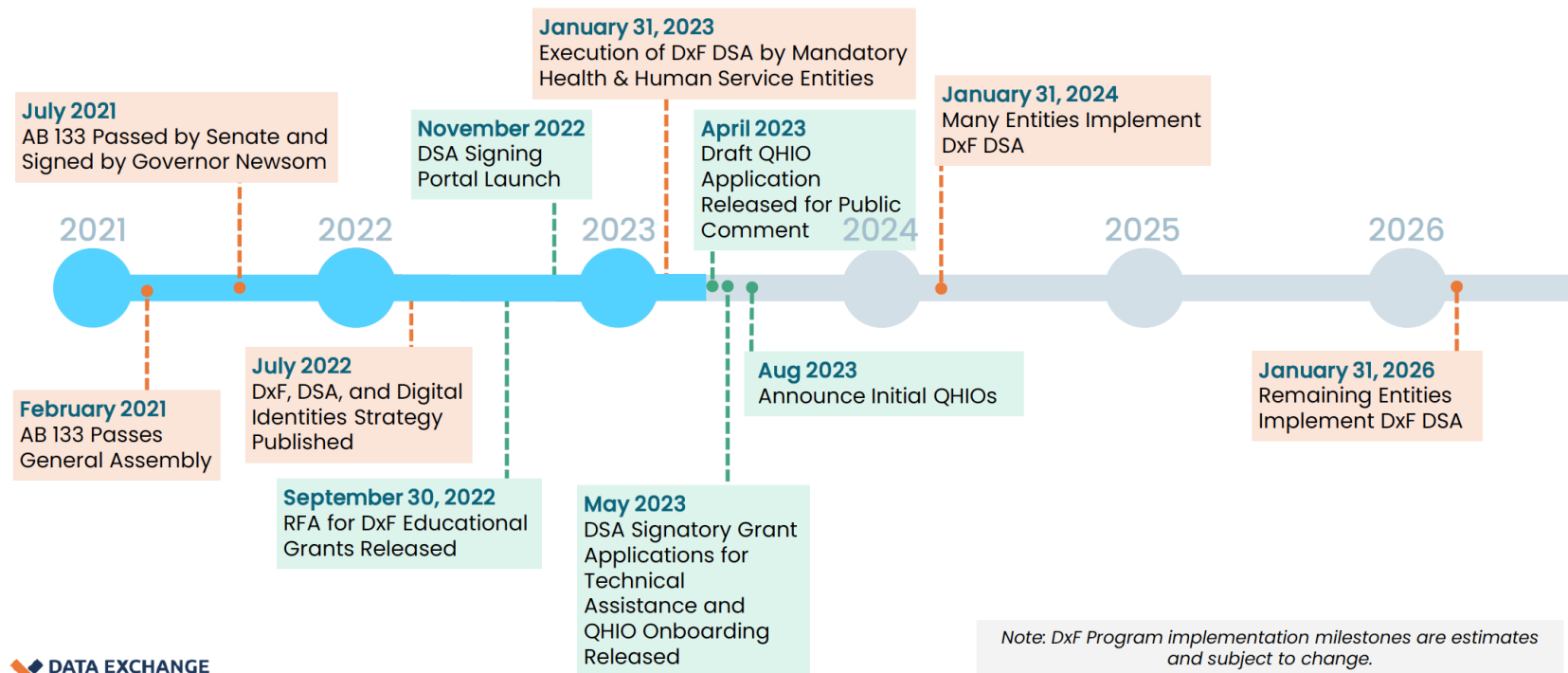
Rules and guidance to support “on the ground” implementation

- ✓ *Detailed implementation requirements*
- ✓ *Will evolve and be refined over time through a participatory governance process involving stakeholders*

The DSA & P&Ps were developed to align with and build upon existing state and federal data exchange laws, regulations, and initiatives where possible (e.g., HIPAA, TECA, CalDURSA).

DxF Implementation Timeline

Past + Upcoming Milestones



The DxP P&Ps - *Reminder*

The DSA's P&Ps provide rules and guidance to support "on the ground implementation." The first set of DSA P&Ps, released in July 2022, include:

#	Topic	Description
1	Amendment of DSA	Sets forth process for amending the DSA.
2	Development of and Modifications to P&Ps	Sets forth process for developing new P&Ps and modifying existing P&Ps.
3	Breach Notification	Sets forth definition of Breach and the obligations of Participants in the event of a Breach, including breach notification timelines.
4	Permitted, Required, & Prohibited Purposes	Sets forth the purposes for which Participants shall, may, and may not exchange HSSI under the DSA.
5	Requirement to Exchange Health & Social Services Information (HSSI)	Sets forth requirements for Participants to exchange HSSI.
6	Privacy and Security Safeguards	Sets forth the privacy standards and security safeguards Participants must comply with in connection with the exchange of HSSI under the DSA.
7	Individual Access Services	Sets forth requirements for Participants to provide Individual Users or their Personal Representatives access to the Individual User's PHI or PII.
8	Data Elements to be Exchanged	Sets forth the data elements that Participants must make available or exchange, at a minimum.



This overview of the P&Ps is intended for educational purposes. Please refer to the full P&Ps posted on the [DxF website](#) for the formal requirements.

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The DxF P&Ps - *Reminder*

The second set of DSA P&Ps, released June 2023, include:

P&P Topic	Purpose
Technical Requirements for Exchange	This P&P describes data exchange patterns for the DxF, those that Participants must support, at a minimum, and the technical standards for access, use, and exchange of Health and Social Services Information (HSSI) to which Participants must adhere.
California Information Blocking Prohibitions	This P&P prohibits all Participants from undertaking any practice likely to interfere with Access, Exchange, or Use of Health and Social Services Information (HSSI) for the required purposes set forth in the Permitted, Required, and Prohibited Purposes P&P.
Early Exchange	This P&P establishes requirements for Participants using the DSA to engage in early exchange of Health and Social Services Information (i.e., participants who engage prior to January 31, 2024).

Source: CalHHS, Joint Implementation Advisory Committee and Data Sharing Agreement Policies and Procedures Subcommittee Meeting #7, June 5, 20223

The DxF P&Ps - *Reminder*

CDII is soliciting input on additional P&Ps that should be considered for development:

For Potential Future Development	Purpose
Dispute Resolution	Describe the process through which disputes between Participants will be reported, mediated, and addressed.
Monitoring & Auditing	Describe monitoring and auditing processes through which Participants will be expected to demonstrate compliance with the DSA and its P&Ps.
Data Quality	Establish expectations for Participants as it pertains to the quality of data exchanged.
Participant Directory	Describe functions of a to-be-established DxF Participant Directory, acceptable use, and Participant obligations for maintenance.



Are there other P&Ps that should be considered for development?

Source: CalHHS, Joint Implementation Advisory Committee and Data Sharing Agreement Policies and Procedures Subcommittee Meeting #7, June 5, 20223



P&P – California Info Blocking Prohibitions

Purpose:

- To support the DxF's commitment to facilitating the timely access, exchange, and use of Health and Social Services Information in compliance with applicable law.

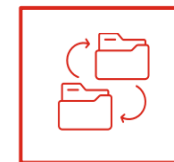
Overview:

- Prohibits Participants **from undertaking any practice that is likely to interfere with access, exchange, or use** of Health and Social Services Information for the Required Purposes set forth in the Permitted, Required and Prohibited Purposes Policy and Procedure.
- No impact on a Participant's obligation, if any, to comply with the Federal Information Blocking Regulations.

P&P – California Info Blocking Prohibitions

What is Info Blocking?

- Generally acts or omissions that may constitute Information Blocking include, but are not limited to, the following:
 - Practices that restrict authorized access, exchange, or use of HSSI under the DSA or applicable law;
 - Implementing HIT in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using HSSI;
 - Implementing HIT in ways that are likely to—(i) restrict the access, exchange, or use of HSSI with respect to exporting complete information sets or in transitioning between HIT systems; or (ii) lead to fraud, waste, or abuse, or impede innovations and advancements in HSSI access, exchange, and use



P&P – California Info Blocking Prohibitions

The P&P incorporates by reference the federal information blocking exceptions under the final rule (ONC Final Rule) adopted by the US Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) under the information blocking provisions of the 21st Century Cures Act.

- Participants deemed in compliance with the P&P if they comply with the Federal Information Blocking Regulations.
 - *Subject to certain exceptions!*
- P&P also notes that a Participant may rely on current and future guidance from the federal government to interpret the requirements of the Federal Information Blocking Regulations.



Comparing the P&P to Federal Info Blocking Rule

Under the Federal Rule, there are **8 regulatory exceptions** that offer assurance that **reasonable and necessary** practices covered by an exception that **ONC does not consider to be information blocking**:



Comparing the P&P to Federal Info Blocking Rule

A participant that is subject to the ONC Final Rule is deemed in compliance with the P&P if the participant meets an information blocking exception to the ONC Final Rule with respect to HSSI, **except that the P&P specifically excludes:**

➤ The Fees Exception

- Participants may generally not rely on the Fees Exception to charge fees for the access, exchange or use of HSSI for a *required* purpose
- However, HIE, HIN, and HIT Participants may still charge other Participants fees for services, provided that such fees are consistent with federal rule and other DxF P&Ps

➤ The Licensing Exception

- Participants may not rely on the Licensing Exception to charge royalties or other fees to license “interoperability elements” to another Participant for the requesting Participant to be able to access, exchange or use HSSI for a *required* purpose
- However, HIE, HIN, and HIT Participants may license “interoperability elements” to other Participants, provided that such licenses are consistent with federal rule



Comparing the P&P to Federal Info Blocking Rule

Participants that are **NOT** covered actors under the ONC Final Rule are generally deemed to be in compliance with the P&P if they meet one of the ONC Final Rule exceptions to the information blocking prohibition, other than the Fees and Licensing Exceptions

- *Note that there are also* minor definitional changes to the Preventing Harm Exception and a requirement that any denial of access under the Privacy Exception be consistent with applicable law and/or the Individual Access P&P.

New! HHS-OIG Final Rule re Info Blocking Penalties for HIT Developers, HINs, and HIEs

The final rule establishes the statutory penalties created by the 21st Century Cures Act. If OIG determines that an individual or entity has committed information blocking, they may be subject up to **a \$1 million penalty** per violation. Only certain entities are subject to an OIG information blocking penalty:

- health IT developers of certified health IT,
 - entities offering certified health IT,
 - health information exchanges, and
 - health information networks.
- The OIG's rule **does NOT establish health care “provider disincentives”**. HHS is developing a separate rule to establish those disincentives (expected Fall 2023).





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Other questions?

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