

CalHHS Data Exchange Framework Policy and Procedure

Subject: Qualified Health Information Organization	
Status:	Policy: OPP-[X]
Publication Date:	Version: 1.0

I. Purpose

California Health and Safety Code section 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. The California Health and Human Services Agency has delegated authority to the Center for Data Insights and Innovation (“CDII”) to establish and manage the Qualified HIO Program. The Qualified HIO Program will, among other things, set forth the requirements an Intermediary must satisfy to be designated as a Qualified HIO under the Qualified HIO Program. The Qualified HIO Program’s designation process is intended to provide Participants with confidence in the organizational structure, service completeness, and technical and programmatic capabilities offered by Qualified HIOs in the event that such Participants choose to engage a Qualified HIO to comply with their obligations under the Data Sharing Agreement (“DSA”). While not required, Participants may choose to engage a Qualified HIO to support them in meeting some or all of their exchange obligations under the DSA. The purpose of this policy is to set forth parameters for the Qualified HIO Program.

II. Policy

This policy establishes the Qualified HIO Program.

This policy shall be effective upon publication of the final version by CDII.

III. Procedures

1. ESTABLISHMENT OF QUALIFIED HIO PROGRAM

a. CDII shall establish, manage, and oversee a Qualified HIO Program that, among other things, shall set forth the requirements for a Participant that is an Intermediary to be designated as a Qualified HIO and any ongoing obligations that a Qualified HIO must meet in order to retain such designation.

2. DESIGNATION OF QUALIFIED HIO

a. An Intermediary that is a Participant and that complies with all requirements set forth by the Qualified HIO Program shall be eligible for designation as a Qualified HIO. Such designation shall require submission by the Intermediary of an application for Qualified HIO status. The application shall be reviewed by CDII for determination of whether the Intermediary will be qualified under the Data Exchange Framework.

3. ONGOING COMPLIANCE REQUIREMENTS

a. In order to maintain its status as a Qualified HIO, an Intermediary must comply with any ongoing or updated obligations set forth by the Qualified HIO Program, including but not limited to signing and complying with the terms of the DSA and complying with the Policies and Procedures.

4. SUSPENSION AND/OR TERMINATION OF QUALIFIED HIO STATUS

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a. In accordance with the Qualified HIO Program, CDII may temporarily suspend or may terminate an Intermediary’s status as a Qualified HIO if it determines the Qualified HIO is not in compliance with requirements set forth by the Qualified HIO Program, including this policy.

i. *Complaint Process.* The Qualified HIO Program shall establish a complaint process by which individuals, entities, or Participants may file a complaint against a Qualified HIO. CDII shall investigate each complaint.

ii. *Appeals Process.* The Qualified HIO Program shall establish an appeals process to allow an Intermediary to appeal an action where CDII has temporarily suspended or has terminated its Qualified HIO status.

IV. Definitions

“**Effective Date**” means the date of publication of the final version of this policy by CDII.

“**Governance Entity**” means the entity within the California Health and Human Services Agency established to oversee the California Data Exchange Framework, the DSA and the Policies and Procedures.

“**Health and Social Services Information**” means 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), anonymized data, pseudonymized data, metadata, digital identities, and schema.

“**HIPAA Regulations**” means the standards for privacy of individually identifiable health information, the security standards for the protection of electronic protected health information and the breach notification rule (45 C.F.R. §§ 160 and 164) promulgated by the U.S. Department of Health and Human Services under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, as in effect on the Effective Date and as may be amended, modified, or renumbered.

“**Intermediary**” means a health information exchange network, health information organization, or technology vendor that assists a Participant in the exchange of Health and Social Services Information and adheres to the standards and policies of the DSA and the Policies and Procedures. An Intermediary may be used by a Participant to allow it to meet some or all of its exchange obligations in the DSA and the Policies & Procedures. Examples might include nationwide networks vendors that provide applicable services, health information organizations (HIOs) including Qualified HIOs, or community information exchanges

“**Participant(s)**” means each health care organization as set forth in California Health and Safety Code § 130290(f) and any other person or organization that is a signatory to the DSA. Participants may include, but are not limited to, a health information network, a community information exchange, a laboratory, a health system, a health information technology (IT) developer, a community-based organization, a payer, a government agency, a research institute, or a Social Services Organization.

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“**Personally Identifiable Information**” or “**PII**” shall have the same meaning as “Personal Information” set forth in Section 1798.140(o) of the California Civil Code, but shall be limited to PII exchanged pursuant to the DSA.

“**Policies and Procedures**” means the policies and procedures adopted by the Governance Entity pursuant to the DSA.

“**Protected Health Information**” or “**PHI**” means “protected health information” as set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations and “medical information” as set forth at Civil Code § 56.05.

“**Qualified HIO**” means an Intermediary designated by CDII that facilitates the exchange of Health and Social Services Information between Participants under the DxF.

“**Qualified HIO Program**” means the requirements made publicly available by CDII that an Intermediary must satisfy to obtain and maintain its designation as a Qualified HIO.

“**Social Services**” means the delivery of items, resources, and/or services to address social determinants of health and social drivers of health, including but not limited to housing, foster care, nutrition, access to food, transportation, employment, and other social needs.

“**Social Services Organization**” means a person or entity whose primary business purpose is to provide Social Services to individuals. Social Services Organizations can include but are not limited to government entities (including multi-department health and human services agencies), community-based organizations, nonprofits, and private entities.

V. References

Qualified HIO Program, available at [\[insert link to Qualified HIO Program materials\]](#).

45 C.F.R. §§ 160 and 164

Health Insurance Portability and Accountability Act (HIPAA) of 1996

California Civil Code § 56.05

California Civil Code §1798.140(o)

California Health and Safety Code § 130290(f)

VI. Version History

No.	Date	Author	Comment
		CalHHS CDII	Pre-publication copy to be shared with DSA P&P Subcommittee