

## CalHHS Data Exchange Framework Policy and Procedure

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| <b>Subject: California Information Blocking Prohibitions</b> |                        |
| <b>Status:</b>   | <b>Policy: OPP-[X]</b> |
| <b>Publication Date:</b>                                     | <b>Version: 1.0</b>    |

### **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 purpose of this policy is to support the Data Exchange Framework’s commitment to facilitating the timely Access, Exchange, and Use of Health and Social Services Information in compliance with Applicable Law.

### **II. Policy**

This policy 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. Any Access, Exchange, and Use of Health and Social Services Information for a Required Purpose shall be without special effort on the part of the user in order to comply with this policy. This policy applies to all Participants.

This policy shall have no impact on or limit a Participant’s responsibility, if any, to comply with the Federal Information Blocking Regulations or other Applicable Law.

This policy shall be effective as of January 31, 2024.

### **III. Procedures**

No Participant shall engage in Information Blocking. This policy applies certain provisions, as set forth below, of the Federal Information Blocking Regulations (45 C.F.R. Part 171, as may be amended) to all Health and Social Services Information Accessed, Used, or Exchanged for a Required Purpose. Participants shall be considered in compliance with this policy if they comply with the Federal Information Blocking Regulations, as outlined below. A Participant may also rely on current and future guidance from the federal government to interpret the requirements of the Federal Information Blocking Regulations.

For the purposes of this policy, when the Federal Information Blocking Regulations use the term “electronic health information,” the term Health and Social Services Information shall also apply.

#### **1. PARTICIPANTS SUBJECT TO THE FEDERAL INFORMATION BLOCKING REGULATIONS**

a. If a Participant is subject to the Federal Information Blocking Regulations (45 C.F.R. Part 171, as may be amended), the Participant shall comply with the Federal Information Blocking Regulations with respect to Health and Social Services Information. The Participant shall be considered in compliance with this policy if the Participant is in compliance with the Federal Information Blocking Regulations, except as follows:

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i. **Fees Exception.** Notwithstanding the fees exception in the Federal Information Blocking Regulations (45 C.F.R. § 171.302) (“Fees Exception”), a Participant may not charge another Participant fees for the Access, Exchange, or Use of Health and Social Services Information for a Required Purpose. However, a Participant that is a Health Information Exchange, Health Information Network, or Health IT Developer of Certified Health IT may charge other Participants fees for its services, provided that such fees are established consistent with the Fees Exception in the Federal Information Blocking Regulations, the Individual Access Services Policy and Procedure, and the Permitted, Required, and Prohibited Purposes Policy and Procedure.

ii. **Licensing Exception.** Notwithstanding the licensing exception in the Federal Information Blocking Regulations (45 C.F.R. § 171.303) (“Licensing Exception”), a Participant may not license Interoperability Elements to another Participant in order for the other Participant to Access, Exchange, or Use Health and Social Services Information for a Required Purpose. However, a Participant that is a Health Information Exchange, Health Information Network, or Health IT Developer of Certified Health IT may license Interoperability Elements to other Participants, provided that such licenses are consistent with the Licensing Exception in the Federal Information Blocking Regulations.

iii. **Content and Manner Exception.** Notwithstanding 45 C.F.R. § 171.301(b)(1)(ii) and 45 C.F.R. § 171.301(b)(2)(ii) and (iii), a Participant may not charge another Participant fees for the Access, Exchange, or Use of Health and Social Services Information for a Required Purpose or license Interoperability Elements to another Participant in order for the other Participant to Access, Exchange, or Use Health and Social Services Information for a Required Purpose except as permitted under Section III(1)(a)(i) and (ii) of this policy.

### 2. **PARTICIPANTS WHO ARE NOT SUBJECT TO THE FEDERAL INFORMATION BLOCKING REGULATIONS**

a. If a Participant is not subject to the Federal Information Blocking Regulations (45 C.F.R. Part 171, as may be amended), the Participant shall still comply with the Federal Information Blocking Regulations with respect to Health and Social Services Information as described in this Subsection 2. A Participant’s Behavior shall not be considered Information Blocking if the Participant meets one of the exceptions from the Federal Information Blocking Regulations, as described below.

b. **Preventing Harm Exception.** A Participant’s Behavior shall not be considered Information Blocking if the Participant meets the conditions of the Preventing Harm Exception (45 C.F.R. § 171.201, as may be amended) in the Federal Information Blocking Regulations. For purposes of this policy:

i. **Type of Risk.** To meet the “Type of Risk” requirement in the Federal Information Blocking Regulations, a Participant may have the risk of harm determined by the professional judgment of a person who has a Professional Relationship with the Individual instead of a licensed health care provider if a Participant does not have a licensed health care provider on staff.

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ii. **Type of Harm.** To meet the “Type of Harm” requirement in the Federal Information Blocking Regulations, a Participant must establish the type of harm was one that could serve as grounds for the Participant to deny access under Applicable Law and/or the Individual Access Services Policy and Procedure.

c. **Privacy Exception.** A Participant’s Behavior shall not be considered Information Blocking if the Participant meets at least one sub-exception of the Privacy Exception (45 C.F.R. § 171.202, as may be amended) in the Federal Information Blocking Regulations. For purposes of this policy:

i. **Denial of an Individual’s Request for their Electronic Health Information.** If an Individual or their Personal Representative requests access to their Health and Social Services Information, a Participant’s denial of the Individual’s request must be consistent with Applicable Law and the Individual Access Services Policy and Procedure.

d. **Security Exception.** A Participant’s Behavior shall not be considered Information Blocking if the Participant meets the conditions of the Security Exception (45 C.F.R. § 171.203, as may be amended) in the Federal Information Blocking Regulations.

e. **Infeasibility Exception.** A Participant’s Behavior shall not be considered Information Blocking if the Participant meets the conditions of the Infeasibility Exception (45 C.F.R. § 171.204, as may be amended) in the Federal Information Blocking Regulations.

f. **Health IT Performance Exception.** A Participant’s Behavior shall not be considered Information Blocking if the Participant meets the requirements of the Health IT Performance Exception (45 C.F.R. § 171.205, as may be amended) in the Federal Information Blocking Regulations. For purposes of this policy, the Health IT Performance Exception shall apply to Health and/or Social Services IT Performance.

g. **Content and Manner Exception.** A Participant’s Behavior shall not be considered Information Blocking if the Participant meets the conditions of the Content and Manner Exception (45 C.F.R. § 171.301, as may be amended) in the Federal Information Blocking Regulations. For purposes of this policy, notwithstanding 45 C.F.R. § 171.301(b)(1)(ii) and 45 C.F.R. § 171.301(b)(2)(ii) and (iii), a Participant may not charge another Participant fees for the Access, Exchange, or Use of Health and Social Services Information for a Required Purpose or license Interoperability Elements to another Participant in order for the other Participant to Access, Exchange, or Use Health and Social Services Information for a Required Purpose except as permitted under Section III(1)(a)(i) and (ii) of this policy.

#### IV. Definitions

Any term used but not capitalized in this policy shall have the same meaning as its capitalized equivalent set forth below.

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“**Access**” means the ability or means necessary to make Health and Social Services Information available for Exchange or Use.

“**Applicable Law**” means all federal, state, local, or tribal laws and regulations then in effect and applicable to the subject matter herein. For the avoidance of doubt, federal government entities are only subject to federal law.

“**Behavior**” means any act or omission by a Participant.

“**DSA**” means the California Health and Human Services Data Exchange Framework Data Sharing Agreement.

“**Exchange**” means the transmittal of Health and Social Services Information between and among different technologies, systems, platforms, or networks.

“**Federal Information Blocking Regulations**” means the regulations set forth in 45 C.F.R. Part 171 (Information Blocking) of the Code of Federal Regulations, as may be amended.

“**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.

“**Health Information Exchange**” means “health information exchange” as set forth in the Federal Information Blocking Regulations (45 C.F.R. § 171.102).

“**Health Information Network**” means “health information network” as set forth in the Federal Information Blocking Regulations (45 C.F.R. § 171.102).

“**Health IT Developer of Certified Health IT**” means “health IT developer of certified health IT” as set forth in the Federal Information Blocking Regulations (45 C.F.R. § 171.102).

“**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 and as may be amended, modified, or renumbered.

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“**Individual**” means a patient or a person who is the recipient of services, including Social Services.

“**Information Blocking**” means any practice that is likely to interfere with Access, Exchange, or Use of Health and Social Services Information for a Required Purpose set forth in the Permitted, Required and Prohibited Purposes Policy and Procedure.

“**Interfere**” or “**Interference**” means to prevent, materially discourage, or otherwise inhibit.

“**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 associated 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 and Procedures. Examples might include nationwide networks or frameworks, vendors that provide applicable services, health information exchange organizations including Qualified HIOs, or community information exchanges.

“**Interoperability Element**” means as defined in 45 C.F.R. § 171.102, as may be amended: hardware, software, integrated technologies or related licenses, technical information, privileges, rights, intellectual property, upgrades, or services that:  
(1) May be necessary to Access, Exchange, or Use electronic health information; and  
(2) Is/Are controlled by the actor, which includes the ability to confer all rights and authorizations necessary to use the element to enable the Access, Exchange, or Use of electronic health information.

“**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.

“**Personal Representative**” means, for purposes of this policy, a person who, under Applicable Law, has authority to act on behalf of an Individual as set forth in 45 C.F.R. § 164.502(g) and Health and Safety Code § 123105(e).

“**Personally Identifiable Information (PII)**” shall have the same meaning as “Personal Information” set forth in Civil Code § 1798.140(v), 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.

“**Professional**” means the person who makes the determination as to the potential risk of harm from releasing Health and Social Services Information. A Professional can be an employee, representative, contractor, or agent of a Participant.

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“**Professional Relationship**” means the Professional has either a current or prior direct working relationship with the Individual or sufficient professional knowledge and interaction with the Health and Social Services Information of the Individual maintained by the Participant to make a determination as to the potential risk of harm from releasing the information. Professional Relationship, as used in this policy, shall specifically exclude Qualified Health Information Organizations or other Intermediaries that facilitate the Exchange of Health and Social Services Information between Participants.

“**Protected Health Information (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 Health Information Organization**” or “**Qualified HIO**” means a state-designated data exchange Intermediary that facilitates the Exchange of Health and Social Services Information between Participants.

“**Required Purposes**” means the purposes for which Participants are required to Exchange Health and Social Services Information as set forth in the Permitted, Required and Prohibited Purposes Policy and Procedure.

“**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.

“**Use**” means the ability for Health and Social Services Information, once Accessed or Exchanged, to be understood and acted upon.

### V. References

45 C.F.R. §§ 160 and 164

45 C.F.R. Part 171

Health Insurance Portability and Accountability Act (HIPAA) of 1996

California Civil Code § 56.05

California Civil Code § 1798.140(v)

California Health and Safety Code § 123105(e)

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California Health and Safety Code § 130290(f)

Individual Access Services Policy and Procedure

Permitted, Required and Prohibited Purposes Policy and Procedure

### VI. Resources

[The Office of the National Coordinator for Health Information Technology. Cures Act Final Rule: Information Blocking Exceptions](#)

### VII. Version History

|  | <b>Date</b> | <b>Author</b> | <b>Comment</b>  |
|--|-------------|---------------|---|
|  |             | CalHHS CDII   | Pre-publication copy to be shared with IAC/DSA P&P Subcommittee |

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