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Key for substantive and administrative changes for the purposes of public comment:

Plain text = existing language unchanged

Blue font with underline = proposed new language, substantive amendment

Red font with strikethrough = proposed language deletion, substantive amendment

Bold font with underline = proposed new language, administrative change

Bold font with strikethrough = proposed language deletion, administrative change

Note: Section headers that appear in bolded and underlined font are not new administrative changes, but were bolded and underlined in the original version of this document.

## I. <u>Purpose</u>

California Health and Safety Code § 130290 was enacted in 2021 and establishes the creation of the California Health & Human Services Data Exchange Framework ("Data Exchange Framework"). The California Health and Human Services Data Exchange Framework ("Data Exchange Framework") Data Exchange Framework requires access to and exchange Exchange of usable Health and Social Services Information by health and social service providers and organizations. The purpose of this policy is to define the Health and Social Services Information to which access Access is to be provided or that is to be exchanged Exchanged by Participants.

#### II. Policy

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

#### 1. DATA TO BE EXCHANGED

- a. Participants shall **make available provide Access to** or **exchange Exchange**, at a minimum, data as defined in the subparagraphs below.
- i. Health Care Providers that are Participants Health care providers, including but not limited to physician practices, organizations, and medical groups, general acute care hospitals, critical access hospitals, long term acute care hospitals, acute psychiatric hospitals, rehabilitation hospitals, skilled nursing facilities, and clinical laboratories, shall provide access Access to or exchange Exchange, at a minimum:
- a. Until October 6, 2022, data elements in the United States Core Data for Interoperability (USCDI) Version 1 if maintained by the entity.
- b. 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 45 C.F.R. § 171.102, including data elements in the United States Core Data for

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<u>Interoperability (USCDI) Version 2</u>, if <u>permitted by Applicable Law and maintained Maintained</u> by the entity.

- ii. County health facilities that are Participants shall provide access Access to or exchange Exchange, at a minimum, the same data required of Health Care Providers health care providers in Paragraph paragraph 1.a.i if permitted under Applicable Law and if maintained Maintained by the entity.
- but not limited to health care service plans and disability insurers that provide hospital, medical, or surgical coverage that are Medi-Cal managed care plans or are regulated by the Department of Managed Health Care or the Department of Insurance, Medi-Cal managed care plans, shall provide access Access to or exchange Exchange, at a minimum, the data required to be shared under the Centers for Medicare and Medicaid Services Interoperability and Patient Access regulations for public programs as contained in United States Department of Health and Human Services final rule CMS-9115-F, 85 FR 25510 including, but not limited to, adjudicated claims, encounter data and clinical data as defined in the USCDI if permitted by Applicable Law and maintained Maintained by the entity.
- a. For Individual Access Services, adjudicated claims and encounter information shall include cost information, specifically provider remittances and enrollee cost-sharing.
- b. For Participants and Purposes other than Except for Individual Access Services, cost information may be omitted.
- c. After October 6, 2022, elinical Clinical data shall include data elements in the United States Core Data for Interoperability (USCDI) Version 2 if permitted by Applicable Law and maintained Maintained by the entity.
- iv. Public health agencies that are Participants shall provide access Access to or-exchange Exchange, at a minimum, the same data required of Health Care Providers health care providers in Paragraph paragraph 1.a.i as if permitted by Applicable Law and maintained Maintained by the entity.
- v. Intermediaries, including but not limited to health information exchange networks and health information organizations, that are Participants shall provide access Access to or-exchange Exchange, at a minimum, all of the following that apply to the extent available, permitted by Applicable Law, maintained Maintained by the entity, and provided by an applicable Participant:
- a. Data defined in **Paragraph** paragraph 1.a.i if providing exchange services to one or more **Health Care Provider(s)** health care provider(s) or county health facility(ies).

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- b. Data defined in **Paragraph** paragraph 1.a.iii if providing exchange services to one or more **Health Plan(s)** health care service plan(s).
- c. Data defined in **Paragraph paragraph** 1.a.iv if providing exchange services to one or more public health agency(ies).
- b. Participants not listed in **Paragraph** paragraph 1.a that voluntarily elect to sign the Data Sharing Agreement ("DSA") shall provide access Access to or exchange Exchange the following Health and Social Services Information:
- i. As applicable and deemed appropriate by the entity for meeting obligations under the **Data Sharing Agreement DSA**, the entity shall provide **access** to or **exchange Exchange**:
- a. Until October 6, 2022, data elements in the United States Core Data for Interoperability (USCDI) Version 1 if appropriate and maintained by the entity.
- a. After October 6, 2022, data Data elements in the <u>United States</u> Core Data for Interoperability (USCDI) Version 2 if appropriate, permitted by Applicable Law, and maintained Maintained by the entity.
- b. Information related to the provision of health care services and/or the provision of social services Social Services if appropriate, permitted by Applicable Law, and maintained Maintained by the entity.
- ii. Data to be **exchanged Exchanged** by Participants not listed in **Paragraph paragraph** 1.a may be the subject of a future revision to this policy developed through a public and transparent process as described in the Development of and Modifications to Policies and Procedures **Policy and Procedure**.
- c. Consistent with Health and Safety Code § 130290(b) and Applicable Law, Participants are not required to Exchange abortion or abortion-related services information as part of data listed in this policy.

#### 2. DATA STANDARDS

- a. Participants shall use standardized data element formats, terminologies, and code sets identified in the *United States Core Data for Interoperability (USCDI) Version 2*.
- b. For data elements not included in USCDI Version 2, such as Electronic Health Information EHI or claims data listed in Paragraph paragraph 1.a, Participants shall use standardized data element formats, terminologies, and code sets identified in applicable national and federally adopted standards National and Federally Adopted Standards, defined as standards published by the US Department of Health and Human Services in the Standards Version Advancement Process.

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c. It is the intent of the Data Exchange Framework to align with national and federally adopted standards. National and Federally Adopted Standards. When conflicts exist between national and federally adopted standards National and Federally Adopted Standards and data formats, terminologies, or code sets mandated by California regulation law or the Policies and Procedures shall prevail.

#### 3. **DATA FORMATS**

- a. Participants shall use national and federally adopted standards National and Federally Adopted Standards in the exchange Exchange of Health and Social Services Information, which shall include one of:
  - i. *HL7 Messaging Standard Version 2.5.1*
- ii. <u>HL7 Clinical Document Architecture (CDA®) Release 2, HL7 Companion</u> Guide to Consolidated Clinical Document Architecture (C-CDA®) 2.1 preferred if applicable
- iii. <u>HL7 Fast Health Interoperability Resources (FHIR®) Release 4.0.1, US</u> <u>Core Implementation Guide 4.0.0 STU4</u> preferred if applicable
- b. Participants shall use standardized data element formats, terminologies, and code sets identified in paragraphs 2.a, 2.b, and 2.c to the extent they are supported by the data formats identified in paragraph 3.a.

### III. <u>Definitions</u>

All capitalized terms shall have the meaning set forth in the Data Exchange Framework Glossary of Defined Terms.

Electronic Health Information shall mean electronic protected health information as defined in 45 CFR 160.103 to the extent that it would be included in a designated record set as defined in 45 CFR 164.501, regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103, but EHI shall not include: (1) psychotherapy notes as defined in 45 CFR 164.501; or (2) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

Maintained with respect to data shall mean that the entity has access to the data, control over the data, and the authority to make the data available, as defined for payers in the CMS Interoperability and Patient Access Final Rule but herein applied to entities beyond payers.

National and Federally Adopted Standards shall mean standards published by the US Department of Health and Human Services in the Standards Version Advancement Process.

United States Core Data for Interoperability shall mean the standardized set of health data classes and constituent data elements for nationwide, interoperable health information

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exchange published by the Office of the National Coordinator for Health Information Technology.

All other capitalized terms, if not defined herein, shall have the same meaning as set forth in the CalHHS Data Exchange Framework Data Sharing Agreement.

#### IV. References

45 CFR § 171.102 - Definitions

California Health and Safety Code § 130290

## Development of and Modifications to Policies and Procedures Policy and Procedure

85 FR 25510 – CMS Interoperability and Patient Access Final Rule, or more properly Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers

HL7 Clinical Document Architecture (CDA®) Release 2

HL7 Companion Guide to Consolidated Clinical Document Architecture (C-CDA®) 2.1

HL7 Fast Health Interoperability Resources (FHIR) Release 4

HL7 Messaging Standard Version 2.5.1

Standards Version Advancement Process

United States Core Data for Interoperability (USCDI)

US Core Implementation Guide 4.0.0 - STU4 Release

#### V. Related Policies and Procedures

See the California Health and Human Services Data Exchange Framework Policy and Procedure on Privacy Standards and Security Safeguards for details on the protection of data elements to be exchanged, including sensitive data elements.

See the California Health and Human Services Data Exchange Framework Policy and Procedure on Development of and Modifications to Policies and Procedures for the public and transparent process for modifying or amending this document.

See the California Health and Human Services Data Exchange Framework Policy and Procedure on Technical Exchange Standards (to be completed) for more information on the

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exchange standards and implementation guides that may be used to access and exchange data elements specified in this document.

# V. <u>Version History</u>

No.	Date	Author	Comment
1.0	July 1, 2022	CalHHS CDII	Final
1.0.1	December 1, 2022	CalHHS CDII	Administrative correction to add "Maintained" to
			requirements for Intermediaries
<u>1.1</u>	<b>TBD</b>	<u>CalHHS</u>	Administrative corrections to align language and use
		<u>CDII</u>	of terms with Glossary of Defined Terms and remove
			standards specified for use prior to October 6, 2022;
			add "as permitted by Applicable Law" to several
			paragraphs, establish precedence of data standards,
			and add provision for HSC § 130290(b)

