

California Health & Human Services Data Exchange Framework

DRAFT Data Sharing Agreement Language

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AUTHORIZATIONS

14.1. Participants shall disclose PHI or PII to another Participant with a legally valid Authorization.

14.2. In order to fulfill **Section 14.1** above, Participants shall engage in one of the below activities:

1. Participants may accept another Participant's representations that a legally valid Authorization has been received. A Participant who has received an Authorization shall be responsible for ensuring the Authorization complies with all Applicable Law. Participants who have received an Authorization are responsible for maintaining documentation as required under Applicable Law and shall 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. Documentation may be submitted physically, electronically, or by facsimile. A Participant who provides assurances that an Authorization is legally valid shall indemnify and hold harmless a Participant who reasonably relied upon the assurances. Participants shall comply with the **Policies and Procedures** related to providing assurances.

2. Before disclosing PHI or PII, Participants may request a copy of an Authorization and shall evaluate the Authorization to ensure it is legally valid within a reasonable time. 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 another Participant that acts upon the Authorization for the lack of legal validity of the Authorization.

14.3. Legally insufficient Authorizations. If a Participant has determined that an Authorization is not legally valid or has been revoked, the Participant shall not disclose PHI or PII but shall inform the Participant requesting PHI or PII that the Authorization is legally insufficient. In no case shall a Participant disclose PHI or PII if an Authorization has been revoked or is legally insufficient.

14.4. Participants shall comply with the **Policies and Procedures/Specifications** for Authorizations.

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SPECIAL COMPLIANCE PROVISIONS AND APPLICABILITY OF HIPAA

5.1. **Addendum A** is incorporated herein by reference and sets forth terms and conditions for a Business Associate Agreement required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It is understood and agreed that **Addendum A** of this Agreement shall be inapplicable to Participants that do not meet the definition of a Covered Entity or Business Associate or the definition of hybrid entity, as that term is defined in 45 C.F.R. part 164.103, and therefore does not impose HIPAA requirements or standards on non-covered entities or non-covered components of hybrid entities unless they are Business Associates.

5.2. Some but not all Participants are either a Covered Entity or a Business Associate. However, not all Participants intend to become each other's Business Associate by virtue of signing this Agreement or exchanging PHI. To support the privacy, confidentiality, and security of PHI, each Participant agrees as follows:

1. 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 Applicable Law.
2. If the Participant is a Business Associate, the Participant does, and shall at all times, 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.
3. If the Participant is a Governmental Participant, the Participant does, and at all times shall, comply with the Applicable Laws, regulations, and policies.
4. If the Participant is a Social Services Organization, the Participant shall comply with Applicable Law and any applicable contract or policy requirements.
5. 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

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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 decided by the **Committee**.

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COOPERATION AND NON-DISCRIMINATION

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

1. Cooperate fully with the **Committee**, each other Participant, and any such third parties with respect to such activities as they relate to this Agreement;
2. Provide such information to the **Committee**, each other Participant, or such third parties as they may reasonably request for purposes of performing activities related to this Agreement;
3. Actively engage in the bilateral or multilateral exchange of information with other Participants as both a consumer and provider of information to the extent permitted or required under this Agreement and Applicable Law;
4. Devote such time as may reasonably be requested by the **Committee** to review information, meet with, respond to, and advise the **Committee** or other Participants with respect to activities as they relate to this Agreement;
5. Provide such reasonable assistance as may be requested by the **Committee** when performing activities as they relate to this Agreement; and
6. 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 **Committee** 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.

6.2. 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 **Committee**, 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.

6.3. Prohibition on Exclusivity. A Participant may not require exclusivity or otherwise prohibit, or attempt to prohibit, any other Participant from joining, exchanging PHI with, conducting other transactions with, using the services of, or supporting another Participant.

6.4. No Discriminatory Limits on Exchange of PHI. 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 PHI with another Participant or Individual User or slows down the rate at which such PHI is sent or received if such limitation or slower rate would have an anti-competitive effect.

6.5. Participants shall comply with **Policies and Procedures** on cooperation and non-discrimination.

DEFINITIONS

“Applicable Law” shall mean: (i) if the Participant is not a federal government entity, all applicable statutes and regulations of the State(s) or jurisdiction(s) in which the Participant operates or exchanges PHI or PII, as well as all applicable federal statutes, and regulations; or (ii) if the Participant is a federal government entity, all applicable federal statutes, regulations, standards, and policy requirements.

“Authorization” shall have the meaning and include the requirements set forth at 45 CFR part 164.508 of the HIPAA Regulations and include any similar but additional requirements under Applicable Law for PHI. Authorization shall also mean the similar requirements under Applicable Law for PII.

“Benefits Determination” shall mean a determination made by any federal or state agency as to whether an individual qualifies for federal or state benefits for any purpose other than health care (for example, Social Security disability benefits) to the extent permitted or required by Applicable Law. Disclosure of PHI for this purpose may require an Authorization if the conditions of 45 C.F.R. part 154.512(k)(6) are not met.

“Breach” shall mean the unauthorized acquisition, access, disclosure, or use of PHI or PII under Applicable Law.

The term “Breach” does not include the following:

1. Any acquisition, access, disclosure, or use of PHI or PII that is encrypted in a manner that conforms with the National Institute of Standards and Technology (NIST) standards specified in Special Publication (SP) 800-57 (as revised from time to time); or
2. Any good faith acquisition, access, disclosure, or use of PHI or PII by an employee or agent of a Participant for the purposes of the Participant provided that the PHI or PII is not used or subject to further unauthorized disclosure consistent with California Civil Code sections 1798.29 and 1798.82; or

3. With regard to Governmental Participants, a disclosure of PHI or PII that is required by law or permitted by California Civil Code section 1798.24 or other Applicable Law.

“Business Associate” shall mean an organization that is defined as a “business associate” in 45 C.F.R. part 160.103 of the HIPAA Regulations.

“Business Associate Agreement” shall mean a contract, agreement, or other arrangement that satisfies the requirements of 45 C.F.R. part 164.504(e), as applicable. With regard to Governmental Participants, a Business Associate Agreement may be a memorandum of understanding.

“Business Planning and Development” shall mean the business planning and development activities of a Covered Entity as described in subsection (5) of the definition of health care operations at 45 C.F.R. part 164.501.

“CalHHS Data Exchange Framework or California Health and Human Services Data Exchange Framework” shall mean a single data sharing agreement and common set of policies and procedures that will govern the exchange of health information among health care and government entities.

“Confidential Participant Information” shall mean proprietary or confidential materials or information of a Discloser in any medium or format that a Discloser labels as such upon disclosure or given the nature of the information or the circumstances surrounding its disclosure, reasonably should be considered confidential. Confidential Participant Information also includes those components of the **Policies and Procedures** that the **Committee** determines should be labeled confidential. Notwithstanding any label to the contrary, Confidential Participant Information does not include any information which is or becomes known publicly through no fault of a Receiving Party; is learned of by a Receiving Party from a third party entitled to disclose it; is already known to a Receiving Party before receipt from a Discloser as documented by the Recipient’s written records;

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or, is independently developed by a Receiving Party without reference to, reliance on, or use of, Discloser's Confidential Participant Information.

"Covered Entity" shall have the meaning set forth at 45 C.F.R. part 160.103 of the HIPAA Regulations. For Participants operating in California, "Covered Entity" shall also include the following as these terms are defined in California Civil Code section 56.05, "provider of health care," "health care service plan," and "licensed health care professional."

"Digital Credentials" shall mean a mechanism that enables Participants to electronically prove their identity and their right to exchange PHI or PII with other Participants.

"Direct Relationship" shall mean a relationship between (a) an Individual User and (b) a Participant, that arises when the Participant offers services to the Individual User in connection with this Agreement and the Individual User agrees to receive such services.

"Discloser" shall mean a Participant that discloses Confidential Participant Information to a Receiving Party.

"Dispute" shall mean any controversy, dispute, or disagreement arising out of or relating to this Agreement.

"Effective Date" shall mean, with respect to the first two Participants to this Agreement, the date on which the second Participant executes this Agreement. For all Participants thereafter, the Effective Date shall be the date that the Participant executes this Agreement in accordance with this Agreement.

"Federal Participants" shall mean those Participants that are federal entities.

“Governmental Participants” shall mean collectively those Participants that are local, state, or federal entities.

“Health Care Operations” shall have the meaning set forth at 45 C.F.R. part 164.501 of the HIPAA Regulations.

“Health Care Provider” shall have the meaning set forth at 45 C.F.R. part 160.103 of the HIPAA Regulations.

“Health Plan” shall have the meaning set forth at 45 C.F.R. part 160.103 of the HIPAA Regulations.

“HIPAA Regulations” shall mean 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. Parts 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 of this Agreement and as may be amended, modified, or renumbered.

“Individual Access Services” shall mean the services provided to satisfy an Individual User’s right to access and to obtain a copy of the Individual User’s PHI and to direct that it be sent to a third party pursuant to: 1) Applicable Law; 2) Any of other Agreement; 3) 45 C.F.R. part 164.524(a) as if it applied to all PHI; 4) 45 C.F.R. part 164.524(c)(2) as if it applied to all PHI; and 5) 45 C.F.R. part 164.524(c)(3)(ii) if the Individual User wants the PHI sent to a third party.

“Individual User” shall mean an actual person who is the subject of the PHI, such as a patient, health plan member, or a patient representative.

“Information Blocking” shall have the meaning set forth in 45 C.F.R. Part 171 and any applicable regulations promulgated thereunder that are then in effect.

“Participants” shall mean any person or organization that is a signatory to this Agreement and: (i) meets the requirements for participation as contained in the Policies and Procedures; (ii) has provided their Digital Credentials. Participants may act as either a Submitter, Recipient, or both when exchanging PHI or PII. Some examples of Participants could include, but are not limited to, a health information network, a community information exchange, a laboratory, a health system, a health IT developer, a community-based organization, a payer, or a government agency.

“Payment” shall have the same meaning as set forth at 45 C.F.R. part 164.501 of the HIPAA Regulations.

“Personally Identifiable Information or PII” shall mean information that can be used to distinguish or trace an individual’s identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Personally Identifiable Information includes but is not limited to bank account number, social security number, driver’s license number, home address, name, gender, ethnicity, and age.

“Policies and Procedures” means the policies and procedures adopted by the CalHHS Data Exchange Framework which are binding on the Participants.

“Protected Health Information or PHI” shall have the combined meaning of “protected health information” as set forth at 45 C.F.R. part 160.103 of the HIPAA Regulations and the meaning of “medical information” as set forth at Civil Code section 56.05.

“Public Health Activities” shall mean an access, use, or disclosure permitted under the HIPAA Regulations and any other Applicable Law for public health activities and purposes, including an access, use, or disclosure permitted under 45 C.F.R. part 164.512(b) and 45 C.F.R. part 164.514(e). Public Health Activities excludes activities

related to oversight or enforcement of laws, regulations, or rules by Governmental Participants.

“Quality Assurance and Improvement” shall mean the quality assessment and improvement activities described in subsection (1) of the definition of health care operations set forth at 45 C.F.R. part 164.501.

“Receiving Party” shall mean a Participant that receives Confidential Participant Information in any capacity including, but not limited to, as a member of the Committee, from a Discloser.

“Recipient” shall mean the Participant(s) that receives PHI or PII from a Submitter. For purposes of illustration only, Recipients include, but are not limited to, Participants who receive queries, responses, subscriptions, publications or unsolicited messages.

“Social Services” shall mean a service or activity performed to support or promote the wellbeing of individuals who face special challenges such as socioeconomic background or physical impairment. Social Services can include but are not limited to goods or services related to housing, transportation, food and nutrition, utilities, education, and older adult services.

“Social Services Organization” shall mean an entity that performs or provides Social Services to individuals. Social Services Organizations can include but are not limited to government entities, community-based organizations, non-profits, and private entities.

“Specifications” shall mean the specifications adopted by the **Committee** pursuant to this Agreement to prescribe the data content, technical, and security requirements to enable the Participants to exchange PHI or PII. Specifications may include, but are not limited to, specific network standards, services, and policies.

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“Submitter” shall mean the Participant(s) who submits PHI or PII to a Recipient. For purposes of illustration only, Submitters include, but are not limited to, Participants who push PHI or PII or send PHI or PII in response to a request.

“Treatment” shall have the same meaning as set forth at 45 C.F.R. part 164.501 of the HIPAA Regulations.

“Utilization Review” shall mean utilization review activities, described in subsection (2)(v) of the definition of payment at 45 C.F.R. part 164.501.

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