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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.

This policy shall have no impact on a Participant's obligation, if any, to comply with the Federal Information Blocking Regulations.

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

III. Procedures

No Participant shall engage in Information Blocking. Practices – acts or omissions – that may constitute Information Blocking include, but are not limited to, the following:

- (a). Practices that restrict authorized access, exchange, or use of Health and Social Services Information under the DSA or Applicable Law;
- (b). Implementing health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using Health and Social Services Information; and
- (c). Implementing health information technology in ways that are likely to—(i) restrict the access, exchange, or use of Health and Social Services Information with respect to exporting complete information sets or in transitioning between health information technology systems; or (ii) lead to fraud, waste, or abuse, or impede innovations and advancements in Health and Social Services Information access, exchange, and use, including care delivery enabled by health information technology.

Notwithstanding the foregoing, a practice shall not be treated as Information Blocking if the Participant satisfies one of the following exceptions:

Preventing Harm.

A Participant's practice that is likely to, or in fact does, interfere with the access, exchange, or use of Health and Social Services Information in order to prevent harm will not be considered Information Blocking when the practice meets the conditions in paragraphs (a) and (b) directly below, satisfies the conditions set forth in either paragraphs (c) or (d) directly below, and also meets the condition in paragraph (e) (if applicable) and (f) directly below.

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- (a). **Reasonable belief.** The Participant engaging in the practice must hold a reasonable belief that the practice will substantially reduce a risk of harm to the individual who is the subject of the Health and Social Services Information affected by the practice or to another natural person that would otherwise arise from the access, exchange, or use of Health and Social Services Information affected by the practice.
- (b) *Practice breadth*. The practice must be no broader than necessary to substantially reduce the risk of harm that the practice is implemented to reduce.
- (c) Type of risk and type of harm (professional judgment). The risk of harm must be determined on an individualized basis in the exercise of professional judgment by a licensed health care professional ¹who has a current or prior relationship with the individual whose Health and Social Services Information is affected by the determination; and the type of harm must be one of the following:
- (1) The request for access is made by the individual's legal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such legal representative is reasonably likely to cause substantial harm to the individual or another person.
- (2) The Health and Social Services Information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person.
- (3) The licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person.
- (d) Type of risk and type of harm (misidentification or mismatch). The risk of harm must arise from data that is known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual whose Health and Social Services Information is affected by the determination or another person.
- (e) Individual right to request review of individualized determination of risk of harm. If access is denied on a ground permitted in accordance with paragraph (c) above, the individual has the right to have the denial (i) reviewed by a licensed health care professional who is designated by the Participant to act as a reviewing official and who did not participate in the original decision to deny; or (ii) reviewed and reversed in accordance with any other applicable Federal, State, or tribal law. The Participant must provide or deny access in accordance with the determination of the reviewing official.
- (f) Practice implemented based on an organizational policy or a determination specific to the facts and circumstances. The practice must be consistent with an organizational policy that

¹ TBD: Whether judgment should be made by a licensed health care professional as set forth in the federal Information Blocking Regulations or whether a broader group should be permitted to make judgment.

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meets paragraph (f)(1) below or, in the absence of an organizational policy applicable to the practice or to its use in particular circumstances, the practice must be based on a determination that meets paragraph (f)(2) below.

- (1) An organizational policy must:
 - (i) Be in writing;
- (ii) Be based on relevant clinical, technical, and other appropriate expertise;
 - (iii) Be implemented in a consistent and non-discriminatory manner; and
- (iv) Conform each practice to the conditions in paragraphs (a) and (b) above, as well as the conditions in paragraphs (c) through (e) above that are applicable to the practice and its use.
 - (2) A determination must:
- (i) Be based on facts and circumstances known or reasonably believed by the Participant at the time the determination was made and while the practice remains in use; and
- (ii) Be based on expertise relevant to implementing the practice consistent with the conditions in paragraphs (a) and (b) above, as well as the conditions in paragraphs (c) through (e) above that are applicable to the Practice and its use in particular circumstances.

Privacy Exception

A Participant's practice of not fulfilling a request to access, exchange, or use Health and Social Services Information in order to protect an Individual's privacy will not be considered Information Blocking when the practice meets all of the requirements of at least one of the sub-exceptions in paragraphs (a) through (c) directly below.

- (a) **Sub-exception State or Federal preconditions not satisfied.** To qualify for the exception on the basis that state or federal law requires one or more preconditions for providing access, exchange, or use of Health and Social Services Information that have not been satisfied, the following requirements must be met:
- (1) The Participant's practice is tailored to the applicable precondition not satisfied, is implemented in a consistent and non-discriminatory manner, and either:
- (i) Conforms to the Participant's organizational policies and procedures that: (A) are in writing; (B) specify the criteria to be used by the Participant to determine when the precondition would be satisfied and, as applicable, the steps that the Participant will take to satisfy the precondition; and (C) are implemented by the Participant, including by providing training on the policies and procedures; or

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- (ii) Are documented by the Participant, on a case-by-case basis, identifying the criteria used by the Participant to determine when the precondition would be satisfied, any criteria that were not met, and the reason why the criteria were not met.
- (2) If the precondition relies on the provision of a consent or Authorization from the individual subject of the Health and Social Services Information and the Participant has received a version of such a consent or Authorization that does not satisfy all elements of the precondition required under applicable law, the Participant must:
- (i) Use reasonable efforts within its control to provide the individual with a consent or Authorization form that satisfies all required elements of the precondition or provide other reasonable assistance to the individual to satisfy all required elements of the precondition; and
- (ii) Not improperly encourage or induce the individual to withhold the consent or Authorization.
- (3) For purposes of determining whether the Participant's privacy policies and procedures and actions satisfy the requirements of paragraphs (a)(1)(i) and (a)(2) directly above when the Participant's operations are subject to multiple laws which have inconsistent preconditions, the Participant shall be deemed to satisfy the requirements of the paragraphs if the Participant has adopted uniform privacy policies and procedures to address the more restrictive preconditions.
- (b) Sub-exception respecting an individual's request not to share information. Unless otherwise required by law, a Participant may elect not to provide access, exchange, or use of an individual's Health and Social Services Information if the following requirements are met:
- (1) The individual requests that the Participant not provide such access, exchange, or use of Health and Social Services Information without any improper encouragement or inducement of the request by the Participant;
 - (2) The Participant documents the request within a reasonable time period;
- (3) The Participant's practice is implemented in a consistent and non-discriminatory manner; and
- (4) The Participant may terminate an individual's request for a restriction to not provide such access, exchange, or use of the individual's Health and Social Services Information only if:
- (i) The individual agrees to the termination in writing or requests the termination in writing;
- (ii) The individual orally agrees to the termination and the oral agreement is documented by the Participant; or
- (iii) The Participant informs the individual that it is terminating its agreement to not provide such access, exchange, or use of the individual's Health and Social Services Information except that such termination is:

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- (A) Not effective to the extent prohibited by applicable federal or state law; and
- (B) Only applicable to Health and Social Services Information created or received after the Participant has so informed the individual of the termination.
- (c) Sub-exception denial of an individual's request for their PHI or PII. A Participant may elect not to provide an individual the right of access to inspect and obtain a copy of PHI or PII about the individual under the circumstances set forth directly below or in the Preventing Harm exception set forth above.
 - (1) A Participant may deny the individual access in the following circumstances.
- (i) The PHI or PII constitutes (A) psychotherapy notes; or (B) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.
- (ii) The PHI or PII is contained in records that are subject to the Privacy Act, <u>5 U.S.C. 552a</u>, or any equivalent state law, and the denial of access under any such law would meet the requirements of that law.
- (iii) The PHI or PII was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

Security Exception

A Participant's practice that is likely to interfere with the access, exchange, or use of Health and Social Services Information in order to protect the security of Health and Social Services Information will not be considered Information Blocking when the practice meets the conditions in paragraphs (a) through (c) of this section, and in addition meets either the condition in paragraph (d) of this section or the condition in paragraph (e) of this section.

- (a) The practice must be directly related to safeguarding the confidentiality, integrity, and availability of Health and Social Services Information.
 - (b) The practice must be tailored to the specific security risk being addressed.
 - (c) The practice must be implemented in a consistent and non-discriminatory manner.
 - (d) If the practice implements an organizational security policy, the policy must -
 - (1) Be in writing;
- (2) Have been prepared on the basis of, and be directly responsive to, security risks identified and assessed by or on behalf of the Participant;

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- (3) Align with one or more applicable consensus-based standards or best practice guidance; and
- (4) Provide objective timeframes and other parameters for identifying, responding to, and addressing security incidents.
- (e) If the practice does not implement an organizational security policy, the Participant must have made a determination in each case, based on the particularized facts and circumstances, that:
- (1) The practice is necessary to mitigate the security risk to Health and Social Services Information; and
- (2) There are no reasonable and appropriate alternatives to the practice that address the security risk that are less likely to interfere with access, exchange or use of Health and Social Services Information.

Infeasibility

A Participant's practice of not fulfilling a request to access, exchange, or use Health and Social Services Information due to the infeasibility of the request will not be considered Information Blocking when the practice meets one of the conditions in paragraph (a) below and meets the requirements in paragraph (b) below.

(a) Conditions -

- (1) Uncontrollable events. The Participant cannot fulfill the request for access, exchange, or use of Health and Social Services Information due to a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.
- (2) Segmentation. The Participant cannot fulfill the request for access, exchange, or use of Health and Social Services Information because the Participant cannot unambiguously segment the requested Health and Social Services Information from Health and Social Services Information that:
- (i) Cannot be made available due to an individual's preference or because the Health and Social Services Information cannot be made available by law; or;
- (ii) May be withheld in accordance with this policy or in accordance with federal or state law.
 - (3) *Infeasible under the circumstances.*
- (i) The Participant demonstrates, prior to responding to the request pursuant to paragraph (b) of this section, through a contemporaneous written record or other documentation its consistent and non-discriminatory consideration of the following factors that led to its determination that complying with the request would be infeasible under the circumstances:

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- (A) The type of Health and Social Services Information and the purposes for which it may be needed;
- (B) The cost to the Participant of complying with the request in the manner requested;
- (C) The financial and technical resources available to the Participant;
- (D) Whether the Participant's practice is non-discriminatory and the Participant provides the same access, exchange, or use of Health and Social Services Information to its companies or to its customers, suppliers, partners, and other persons with whom it has a business relationship;
- (E) Whether the Participant owns or has control over a predominant technology, platform, health information exchange, or health information network through which Health and Social Services Information is accessed or exchanged; and
- (F) Why the Participant was unable to provide access, exchange, or use of Health and Social Services Information consistent with this Policy and Procedure, including consideration of whether the Participant would be able to fulfill the request in an alternative manner than the one requested.
- (ii) In determining whether the circumstances were infeasible under paragraph (a)(3)(i) above, it shall not be considered whether the manner requested would have:
 - (A) Facilitated competition with the Participant.
 - (B) Prevented the Participant from charging a fee or resulted in a reduced fee.
- (b) **Responding to requests.** If a Participant does not fulfill a request for access, exchange, or use of Health and Social Services Information for any of the reasons provided in paragraph (a) above, the Participant must, within ten (10) business days of receipt of the request, provide to the requestor in writing the reason(s) why the request is infeasible.

Health and Social Services IT Performance Exception

A Participant's practice that is implemented to maintain or improve health and/or social services IT (referred to collectively herein as "health IT") performance and that is likely to interfere with the access, exchange, or use of Health and Social Services Information will not be considered Information Blocking when the practice meets a condition in paragraph (a), (b), or (c) below, as applicable to the particular practice and the reason for its implementation.

(a) *Maintenance and improvements to health IT.* When the Participant implements a practice that makes health IT under the Participant's control temporarily unavailable, or temporarily

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degrades the performance of health IT, in order to perform maintenance or improvements to the health IT, the Participant's practice must be –

- (1) Implemented for a period of time no longer than necessary to complete the maintenance or improvements for which the health IT was made unavailable or the health IT's performance degraded;
 - (2) Implemented in a consistent and non-discriminatory manner; and
- (3) If the unavailability or degradation is initiated by a health IT developer of certified health IT, health information exchange, or health information network:
- (i) Planned. Consistent with existing service level agreements between the individual or entity to whom the health IT developer of certified health IT, health information exchange, or health information network supplied the health IT; or
- (ii) Unplanned. Consistent with existing service level agreements between the individual or entity; or agreed to by the individual or entity to whom the health IT developer of certified health IT, health information exchange, or health information network supplied the health IT.
- (b) **Practices that prevent harm.** If the unavailability of health IT for maintenance or improvements is initiated by a Participant in response to a risk of harm to an Individual or another person, the Participant does not need to satisfy the requirements of this *Health IT Performance* exception, but must comply with all requirements of the *Preventing Harm* exception set forth above at all relevant times to qualify for an exception.
- (c) **Security-related practices.** If the unavailability of health IT for maintenance or improvements is initiated by a Participant in response to a security risk to Health and Social Services Information, the Participant does not need to satisfy the requirements of this *Health IT Performance* exception, but must comply with all requirements of the *Security* exception as set forth above at all relevant times to qualify for an exception.

IV. Definitions

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

- "Access" means the ability or means necessary to make Health and Social Services Information available for exchange or use.
- "Exchange" means the ability for Health and Social Services Information to be transmitted between and among different technologies, systems, platforms, or networks.
- "Information Blocking" means a practice that is likely to interfere with access, exchange, or use of Health and Social Services Information and (1) if conducted by a health IT developer of certified health IT, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of Health

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and Social Services Information; or (2) if conducted by any other Participant, such Participant knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of Health and Social Services Information.

"Federal Information Blocking Regulations" shall refer to regulations set forth in Part 171 (Information Blocking) of Title 45 of the Code of Federal Regulations. For purposes of this policy, any reference to Electronic Health Information set forth in Part 171 (Information Blocking) of Title 45 of the Code of Federal Regulations shall be interpreted to mean Health and Social Services Information.

"Interfere with" or "interference" means to prevent, materially discourage, or otherwise inhibit.

"Use" means the ability for Health and Social Services Information, once accessed or exchanged, to be understood and acted upon.

V. References

VI. Version History

Date	Author	Comment
October 22,	CalHHS CDII	Draft for DxF Data Sharing Agreement Subcommittee
<mark>2022</mark>		review