

126040 Transparency and Complaint Process

(a)

Prior to the approval of any demonstration project, the Applicant must provide CalOHII with copies of: (1) The Applicant's Notice of Privacy Practices created pursuant to 45 C.F.R. § 164.520. (2) The Applicant's Participants Agreement and a list of the entities included in the agreement. (3) A description of the Applicant's complaint mechanism required by § 126040(d), including any documentation or patient educational materials related to the complaint process.

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The Applicant's Notice of Privacy Practices created pursuant to 45 C.F.R. § 164.520.

(2)

The Applicant's Participants Agreement and a list of the entities included in the agreement.

(3)

A description of the Applicant's complaint mechanism required by § 126040(d), including any documentation or patient educational materials related to the complaint process.

(b)

Once a demonstration project is approved, but prior to the start of the demonstration project, within a specified time frame negotiated with and approved by CalOHII, the Demonstration Project Participant must provide: (1) If the Demonstration Project Participant is a HIO, a list of all parties who have signed the

HIO's Participant Agreement, with their contact information and a general description of the service(s) provided, including the data shared, the purpose, and whether further dissemination of the data is allowed, regardless of whether the information is de-identified. (2) If the Demonstration Project Participant is not a HIO, a list of all of the Participant's current business associates with electronic access to individual health information disclosed through the demonstration project, with their contact information and a general description of the service(s) provided, including the data shared, the purpose, and whether further dissemination of the data is allowed, regardless of whether the information is de-identified. (3) If a new business associate is added after the start of the project, or a business associate agreement is modified, the Demonstration Project Participant must provide CalOHII with an updated list quarterly. (4) In CalOHII's discretion, CalOHII may require copies of the Demonstration Project Participant's business associate agreements be provided to CalOHII. The Participant shall provide copies within five working days from the receipt of written request from CalOHII.

(1)

If the Demonstration Project Participant is a HIO, a list of all parties who have signed the HIO's Participant Agreement, with their contact information and a general description of the service(s) provided, including the data shared, the purpose, and whether further dissemination of the data is allowed, regardless of whether the information is de-identified.

(2)

If the Demonstration Project Participant is not a HIO, a list of all of the Participant's current business associates with electronic access to individual health information disclosed through the demonstration project, with their contact information and a general description of the service(s) provided, including the data shared, the purpose,

and whether further dissemination of the data is allowed, regardless of whether the information is de-identified.

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(c)

All unauthorized electronic disclosures or access of individual health information shall be reported by the Demonstration Project Participant to CalOHII within thirty (30) business days of the detection of the unauthorized access or disclosure. Good faith acquisition of IHI by an employee or agent within the course of coordinating care or delivering treatment services, provided that IHI is not used or subject to further unauthorized disclosure do not need to be reported. A report to CalOHII under this provision does not relieve the Demonstration Project Participant from any requirement under any local, state, or federal law.

(d)

A Demonstration Project Participant must ensure there is a mechanism to receive and respond to patient complaints.(1) Complaints associated with the demonstration project shall be reported and forwarded to CalOHII quarterly and include the Demonstration Project Participant's response to any complaint regarding the demonstration project. (2) Complaints reflecting significant risk to patient privacy and confidentiality of individual health information or patient health

and safety attributable to the demonstration project shall be reported by the Demonstration Project Participant to CalOHII immediately.

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