

<b>TITLE: Operational Policy and Procedure Development and Approval</b>	
Policy #: HEN-002	Effective Date: May 15, 2013
Program: Hawai'i HIE	Revision Date: July 15, 2015
Approved By: Hawai'i HIE Board of Directors	

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### 1. Purpose

This policy defines the development, amendment and approval process for the Hawai'i HIE Operational Policies governing participation with the Hawai'i HIE and use of the Hawai'i HIE's Health eNet system ("Health eNet", the "System").

### 2. Scope

This policy applies to: 1) the Hawai'i HIE and all of its workforce members, 2) all Health eNet Authorized Users, 3) all Hawai'i HIE business associates, subcontractors, and 4) all Hawai'i HIE Participants.

In particular, this policy addresses the means to implement Operational Policies that govern Hawai'i HIE's, Participants', and Health eNet Authorized Users' responsibilities and accountabilities related to the Health eNet; and to the data, including but not limited to individuals' protected health information (PHI), requested, accessed, used and disclosed via the System.

The Operational Policies are not intended to replace or supersede Participants' policies related to processes and systems not owned or administered by the Hawai'i HIE.

### 3. Definitions

**Data Access and Management Committee.** Hawai'i HIE standing domain committee comprised of Hawaii HIE directors and staff members, and stakeholder and community representatives, chartered to develop and review procedures regarding information privacy and security, and data access applicable to the Hawai'i HIE.

**Legal/Policy Committee.** Hawai'i HIE standing domain committee comprised of Hawai'i HIE directors and staff members, and stakeholder and community representatives, chartered to develop and review all legal policies regarding information privacy and security, and data access applicable to the Hawai'i HIE.

**(The) Office of the National Coordinator for Health Information Technology (ONC).** A federal agency within the U.S. Department of Health and Human Services ("HHS") that supports the adoption and promotion of health information technology and nationwide health information exchange to improve the healthcare of the U.S. population.

**(The) Office for Civil Rights (OCR).** A federal agency within the U.S. Department of Health and Human Services ("HHS") that, among other duties, enforces the various HIPAA Rules.

### 4. Policy and Procedures

#### 4.1. Development, Amendment, Review and Approval of Operational Policies.

**4.1.1. Developing and Amending Operational Policies.** The Hawai'i HIE will develop and amend Operational Policies as necessary, primarily based on ongoing review of applicable laws; policies and procedures of other health information organizations (HIOs); and requirements, standards and guidance provided by the U.S. Department of Health and Human Services (such as publications from the OCR and ONC) and the State of Hawaii.

Procedure
1. If necessary, the Compliance and Privacy Officer will convene a working group consisting of Hawai'i HIE staff and stakeholder representatives to draft and review substantive amendments to the Hawai'i HIE's Operational Policies, and to develop new Operational Policies.

**4.1.2. Role of the Hawai'i HIE Legal/Policy Committee.** The Legal/Policy Committee is responsible for identifying specific policy needs regarding participation with the Hawai'i HIE and use of the Health eNet, and soliciting stakeholder feedback and recommendations regarding the development of new Operational Policies and substantive amendments to existing Operational Policies. The Committee is also responsible for drafting, reviewing and recommending such new or substantively amended Operational Policies for consideration, approval and adoption by the Board of Directors.

Procedure
1. New and substantively updated Operational Policies will be placed on the Legal/Policy Committee agenda for consideration, as needed.
2. The draft documents will be presented to the Legal/Policy Committee for the Committee's review and recommendations to the Board of Directors for consideration, approval and adoption of the new or updated Operational Policies.

**4.1.3. Role of the Hawai'i HIE Board of Directors.** The Board of Directors is responsible for reviewing recommended new and substantively amended Operational Policies and determining, by a procedure of formal approval, if they should be approved and adopted as official policies of the Hawai'i HIE.

Procedure
2. Operational Policies must be approved by majority vote of the Hawai'i HIE Board of Directors.

**4.2. Development, Amendment, Review and Approval of Operational Procedures.**

**4.2.1. Developing and Amending Operational Procedures.** The Hawai'i HIE will develop and amend Operational Procedures as necessary, primarily based on updates to Operational Policies, business services and processes, and information systems.

Procedure
1. The Hawai'i HIE Executive Director and Hawai'i HIE Compliance and Privacy Officer shall ensure that, if necessary, a working group consisting of Hawai'i HIE staff and stakeholder representatives is convened to review and draft substantive changes to the Hawai'i HIE's Operational Procedures, and to develop new Operational Procedures.

**4.2.2. Role of the Hawai'i HIE Data Access and Management Committee.** The Data Access and Management Committee may assist the Hawai'i HIE in drafting, reviewing and recommending Operational Procedures for consideration and approval by the Hawai'i HIE directors who are members of the Data Access and Management Committee.

**4.3. Role of the Hawai'i HIE Executive Director.** The Executive Director is responsible for ensuring the development, amendment, approval and implementation of the Hawai'i HIE's Operational Policies and Procedures.

Procedure
1. The Hawai'i HIE Executive Director works with the Hawai'i HIE Compliance and Privacy Officer as necessary to prepare Operational Policies, as developed or amended from time to time, for consideration, approval and adoption by the Hawai'i HIE Board of Directors.

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| <ul style="list-style-type: none"><li>• Draft documents shall be circulated to the Board of Directors at least one week prior to the scheduled date of the meeting when voting will take place.</li></ul>   |
| <ol style="list-style-type: none"><li>2. The Executive Director works with the Compliance and Privacy Officer as necessary to prepare Operational Procedures, as developed or amended from time to time, for consideration, approval and adoption by the Hawai'i HIE directors who are members of the Hawai'i HIE Data Access and Management Committee.</li></ol> |

**4.4. Ongoing Review and Amendment of Operational Policies and Procedures.** Operational Policies and Procedures shall be reviewed on a regular basis, but no less frequently than every three (3) years and as necessary to address changes to applicable laws affecting participation with the Hawai'i HIE or use of the Health eNet.

Operational Policies and Procedures shall be amended as necessary following such review, in accordance with sub-sections 4.1, "Development, Amendment, Review and Approval of Operational Policies", and 4.2, "Development, Amendment, Review and Approval of Operational Procedures", above.

**4.4.1. Minor Amendments to Operational Policies or Procedures.** The Hawai'i HIE may make minor amendments to Operational Policies or Procedures as necessary from time to time. Examples of minor amendments include: technical-writing edits to address typographical and syntax errors, additions or modifications to definitions, updates or corrections to terminology, and changes to the formatting of a policy-and-procedure document.

Directors who are members of the Legal/Policy Committee and Data Access and Management Committee determine if a given change to an Operational Policy or Procedure is substantive or minor in nature on behalf of their respective committees, pursuant to the Hawai'i HIE by-laws.

<b>Procedure</b>
<ol style="list-style-type: none"><li>1. The Hawai'i HIE Executive Director and Hawai'i HIE Compliance and Privacy Officer shall ensure that the following notifications are made regarding proposed minor amendments to Operational Policies and Procedures:<ul style="list-style-type: none"><li>• The directors who are members the Legal/Policy Committee shall be notified of minor amendments to Operational Policies.</li><li>• The directors who are members of the Data Access and Management Committee shall be notified of minor amendments to Operational Procedures.</li></ul></li></ol>

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| <p>2. The directors who are members of a Committee shall review the proposed minor amendments for approval on behalf of the Hawai'i HIE.</p> <ul style="list-style-type: none"><li>• If the majority of the directors, on behalf of a Committee, approve the amendments as minor, the Hawai'i HIE will document and retain such approval per sub-section 4.6, "Retention of Operational Policies and Procedures", then proceed to provide notifications per sub-section 4.5, "Notifications Regarding New or Updated Operational Policies and Procedures".</li></ul> |
| <ul style="list-style-type: none"><li>• If the majority of the directors, on behalf of a Committee, determine that an amendment is substantive rather than minor, then, as applicable, the Hawai'i HIE will follow the necessary review-and-approval procedures in sub-section 4.1, "Development, Amendment, Review and Approval of Operational Policies", and/or sub-section 4.2, "Development, Amendment, Review and Approval of Operational Procedures".</li></ul>  |

**4.5. Notifications Regarding New or Updated Operational Policies and Procedures.** The Hawai'i HIE will notify its workforce members and Participants of any policy and/or procedure changes via the Hawai'i HIE website. It is the responsibility of each Hawai'i HIE workforce member, Participant and Health eNet Authorized User to review and be in compliance with the most current versions of the Operational Policies and Procedures.

Procedure
<p>1. The Hawai'i HIE Executive Director and Compliance and Privacy Officer shall ensure that all newly approved and adopted Operational Policies and Procedures will be posted on the Hawai'i HIE website and that the following notifications are made regarding changes to the Operational Policies and Procedures within two (2) weeks of approval by the Board of Directors.</p> <ul style="list-style-type: none"><li>• The Hawai'i HIE will provide Health eNet Authorized Users notification of and instructions for accessing new or updated Operational Policies and Procedures upon System logon.</li><li>• The Hawai'i HIE will provide Hawai'i HIE workforce members notification of and instructions for accessing new or updated Operational Policies and Procedures via internal communications (e.g. e-mail, staff meetings, staff trainings).</li></ul>

**4.6. Retention of Operational Policies and Procedures.** An archived version of each Operational Policy, and its respective Operational Procedures implemented by the Hawai'i HIE, shall be retained for a minimum of six (6) years from the date last in effect.

Procedure
<p>1. The Hawai'i HIE Executive Director and Compliance and Privacy Officer shall ensure that a system of cataloging and archiving revised and inactive Operational Policies and Procedures, and the approvals of such Policies and Procedures by the Hawai'i HIE's directors, will be maintained.</p>

**5. Revision History**

<b>Revision Date</b>	<b>Revision Type*</b>	<b>Author(s)</b>	<b>Revision Rationale, Description</b>	<b>Approved by</b>
May 15, 2013	New	Legal/Policy Committee	Initial version of policy	Hawai'i HIE Board of Directors
July 15, 2015	Amendment	Legal/Policy Committee	Table of contents, section numbering, "Definitions" section, and "Development, Amendment, Review and Approval of Operational Procedures" section added, policy title edited	Hawai'i HIE Board of Directors

\* Revision Type options = New, Amendment, Minor Amendment, Consolidation (i.e. merging of multiple policies)