

TITLE: Participating Entity Registration and Compliance Requirements	
Policy #: HEN-003	Effective Date: April 4, 2012
Program: Hawai'i HIE	Revision Date: July 14, 2016
Approved By: Hawai'i HIE Board of Directors	

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1. Purpose

This policy defines the requirements for an entity (i.e. business, organization, government entity) to apply for and be accepted as a Participant of the Hawai'i HIE, and receive access to the Hawai'i HIE's Health eNet system ("Health eNet", the "System").

2. Scope

This policy applies to health care organizations and other entities that are seeking acceptance by the Hawai'i HIE to utilize one or more of the Hawai'i HIE's Health eNet ("Health eNet", the "System") service lines.

This policy does not apply to "individual participation", i.e. the availability of an individual's protected health information (PHI) via the Health eNet, and the individual's right to request a change to the availability of his/her PHI. Individual participation is addressed in the Hawai'i HIE's *Individual Rights* (HEN-008) and *Individual Notice and Participation* (HEN-009) Operational Policies and Procedures.

3. Definitions

Compliance (as it pertains to Hawai'i HIE participation). Adherence by a Participant to all requirements of section 4 of this Operational Policy and Procedure applicable to the Participant.

Data Contributor. A Participant that is authorized to provide data and information to other Participants via the Health eNet. Primarily refers to a Participant contributing information to the Health eNet Community Health Record (CHR).

Data Recipient. A Participant that is authorized to receive or obtain information via the Health eNet.

Data Sharing Agreement (DSA) / Participation Agreement (PA). The documented agreement made by and between Hawai'i HIE and each Participating Entity, which sets forth the terms and conditions, rights and responsibilities regarding participation with the Hawai'i HIE and use of the Health eNet. DSAs must be used if a Participant will contribute data to the CHR.

Participant, Participating Entity. An organization or other entity that has entered into a written agreement with the Hawai'i HIE to act as a data contributor, data recipient or both – utilizing one or more of the Hawai'i HIE's information-exchange service lines. A Participating Entity must meet the requirements for participating with the Hawai'i HIE set forth in the Hawai'i HIE's Operational Policies and Procedures.

Registrant. An organization or other entity undertaking the process of registering to become a Hawai'i HIE Participant.

Service Lines (Health eNet). Information-exchange service lines provided by the Hawai'i HIE as part of the Health eNet. For a list or description of current Health eNet service lines, please contact the Hawai'i HIE. Information about current service lines may also be found on the Hawai'i HIE's website at: <http://www.hawaiihie.org/providers>.

4. Policy and Procedures

Entities registering to become Health eNet Participants must meet the following requirements, as applicable on a case-by-case basis, to use the Health eNet.

4.1. Registering for Participation – General Requirements

4.1.1. Types of Entities Allowed to Register for Participation. Each entity registering to become a Health eNet Participant must be one of the following types of entities:

- HIPAA covered entity (CE), i.e. healthcare provider or health plan
- HIPAA business associate (BA) of a CE
- Subcontractor of a BA
- Public health agency
- Entity operating under the authority of a public health agency, e.g. a cancer registry

- A third-party recipient of PHI, as permissible under and in compliance with HIPAA and other applicable laws
- Hybrid Entities – Only “operational components” within hybrid entities, as defined and specified by HIPAA, that are one of the preceding entity types may apply to become Participants; e.g. a pharmacy within a retail establishment.
- Other third-party recipient of PHI, e.g. patient educator – Such third-parties shall provide a use case for review and approval by the Hawai'i HIE's Legal/Policy Committee.

4.1.2. Types of Providers and Non-Providers Allowed to Register for Participation.

Registrants must be one of the entity types listed in Appendix A, “Availability of Health eNet Service Lines by Entity Type”, which is attached for reference but is separate from this Operational Policy. A registrant may register to participate in one or more of the service lines specified for its entity type in Appendix A.

The Hawai'i HIE may periodically amend the list of the types of entities that may participate in the Health eNet.

4.1.3. Excluded Entities and Individuals. A registering entity must not be excluded from participation in federally subsidized programs.

If a registrant conducts business in the State of Hawaii, then the registrant must be in good standing regarding the State's requirements to lawfully conduct business in Hawaii.

If a registrant requires a professional/vocational license to practice medicine or otherwise perform a professional service relevant to the registrant's participation with the Hawai'i HIE, then the registrant must hold a current, valid license from the State of Hawaii, or otherwise be legally authorized to deliver medical services in the State of Hawaii, based on the availability of Health eNet services according to Appendix A.

Registrants must also ensure that their workforce members who intend to become Authorized Users of the Health eNet: 1) are not excluded from participation in federally subsidized programs, and 2) if applicable, hold current valid professional/vocational licenses issued by the State of Hawaii, or otherwise be legally authorized to deliver medical services in the State of Hawaii, based on the availability of Health eNet services according to Appendix A.

Entities that do not meet the requirements of this section will be excluded from participation with the Hawai'i HIE. Individuals who do not meet the requirements of this section will be excluded from provisioning as Authorized Users.

Participants are required to notify the Hawai'i HIE regarding any Authorized Users who no longer meet the provisions of this section.

Procedure
1. The Hawai'i HIE will screen registrants and their prospective Health eNet Authorized Users against federal exclusion lists and State of Hawaii business registration and professional/vocational licensing data, upon registration and periodically going forward.

4.1.4. Health eNet Registration for Participation. Each registrant must complete a Health eNet registration process.

A current Participant may register to use one or more Health eNet service lines. Information about current service lines may be found on the Hawai'i HIE's website at: <http://www.hawaiihie.org/providers>.

Procedure
<p>1. During the registration process, prospective and current Participants shall provide the Hawai'i HIE, at a minimum:</p> <ul style="list-style-type: none"> • Name and address of entity, including: <ul style="list-style-type: none"> ○ The legal entity name and address, as registered in the legal jurisdiction where the entity conducts its operations ○ The official e-mail address for the organization • Type of entity, as determined using the above criteria in this subsection • Entity's and its respective Authorized Users' National Provider Identifier (NPI) numbers (if applicable) • Acceptable statement describing intended use(s) of the Health eNet service line(s). The registrant's intended use(s) of the Health eNet must be acceptable to the Hawai'i HIE. Patient treatment, payment, and care coordination are acceptable uses, while other intended uses will be evaluated to ensure they are legal and allowed per the Hawai'i HIE's operational policies and guidelines. The registrant's choice of service line(s) also factors into determining appropriate minimum use requirements of the System, as specified by HIPAA. • Points of contact. Points of contact serve as liaisons between a Participant and the Hawai'i HIE for contractual, operational and compliance purposes. A registrant may designate a given individual to serve as multiple points of contact, based on the registrant's preference and/or the number of its workforce members available to fulfill these roles: <ul style="list-style-type: none"> ○ Contract signatory name and contact information: The contract signatory must have legal authority on behalf of his/her entity to execute a Data Sharing Agreement or Participation Agreement with the Hawai'i HIE. The contract signatory may also designate a representative (e.g. an executive assistant) to serve as the point of contact for the signatory. ○ Primary Point of Contact name and contact information: The Primary Point of Contact is the main point of contact between

<p>the Hawai'i HIE and a Participant regarding Health eNet operations.</p> <ul style="list-style-type: none"> ○ Site Administrator name and contact information: The Site Administrator performs duties related to Authorized User access management, as directed by the Participant. The Site Administrator may be the Hawai'i HIE, based on agreement between the Participant and the Hawai'i HIE. The responsibilities of the Site Administrator are further described in the Hawai'i HIE's <i>Access Management</i> (HEN-005) Operational Policy. ○ Privacy Officer name and contact information (if applicable): Organizations that are CEs must designate a Privacy Officer. ○ Security Officer name and contact information (if applicable): Organizations that are CEs utilizing and intending to contribute or receive electronic PHI via the Hawai'i HIE's services must designate a Security Officer. ○ Incident Response Point of Contact name and contact information: The Incident Response Point of Contact is responsible for receiving notifications from the Participant's workforce members regarding events that may involve unauthorized activities that adversely affect individuals, the Health eNet, the Hawai'i HIE and/or Participants. Please see the Incident Response and Mitigation policy for additional information.
<p>2. The Hawai'i HIE will work with the registrant as needed to identify which Health eNet service lines the registrant is eligible to use that are beneficial to the registrant.</p>
<p>3. The Hawai'i HIE will verify that the registrant meets the requirements set forth in section 4.1.</p>

4.2. Registering for Participation – Registrant-Specific Requirements

Once the Hawai'i HIE has verified that a registrant meets all of the above General Registration Requirements, registrants must meet requirements based on their respective entity types.

Procedure
<p>1. Each registrant must meet additional documentation requirements, as follows:</p> <ul style="list-style-type: none"> • Registrants will utilize Appendix B, "Required Registrant Documentation for Health eNet Participation", which is attached for reference but is separate from this Operational Policy, to determine which specific documents are required. Appendix B also specifies which required documents the registrant must submit to the Hawai'i HIE, and in which cases a registrant may provide a written attestation to the Hawai'i HIE that the registrant possesses the document in lieu of submitting the document.

<ul style="list-style-type: none"> • If a registrant plans to contribute information to or receive information via the Health eNet using an electronic health record (EHR) system, then the EHR system must be certified for Meaningful Use, as provided for in the HITECH Act and further defined by the Department of Health and Human Services. • If a registrant plans to establish a secure conduit via the Health eNet, then the registrant must work with the Hawai'i HIE to verify that all required specifications for data transmission and interface development are met.
2. The Hawai'i HIE will assist registrants, as necessary, to determine if a given document is required, e.g. in the event the need for a document depends on the registrant's entity type or purpose for using the Health eNet.

4.3. Acceptance, Rejection and Re-Consideration of Registrants

The Hawai'i HIE will base its decision to accept or reject a registrant as a Participant on the registrant's adherence to the requirements set forth in this policy.

4.3.1. Acceptance.

Procedure
1. If a registrant is accepted by the Hawai'i HIE, the registrant shall sign a Data Sharing Agreement or Participation Agreement with the Hawai'i HIE and other required participation documents, as specified in Appendix B.
2. The Hawai'i HIE will then work with the new Participant to verify that all other required technical specifications and criteria are met for the Participant's use of the selected Health eNet service line(s).

4.3.2. Rejection and Re-Consideration.

Procedure
1. The Hawai'i HIE will notify the registrant of the decision, including any identified deficiencies in meeting registration requirements in the event of a rejection.
2. If a registrant is rejected by the Hawai'i HIE, a registrant may correct the deficiencies in meeting the registration requirements identified by the Hawai'i HIE, then complete the registration process again to be re-considered for participation.

More detailed information about the Hawai'i HIE's process for reviewing registrants' qualifications as Participants may be found on the Hawai'i HIE's website at: <http://www.hawaiihie.org/policies>.

4.4. Ongoing Compliance with Participation Requirements

Participants are required to maintain ongoing compliance with the requirements of this Operational Policy and its Procedures in order to retain Health eNet participation, and notify

the Hawai'i HIE of any non-compliance with the provisions of this policy and/or its procedures.

In the event the Hawai'i HIE determines that a Participant is no longer in compliance with the requirements of this policy, the Hawai'i HIE may suspend a Participant and Participant's Authorized Users from using or connecting to the Health eNet, terminate such System access, and/or terminate the Data Sharing Agreement or Participation Agreement with a Participant.

Please see the Hawai'i HIE *Participation Suspension, Termination and Reinstatement* (HEN-004) Operational Policy for additional information regarding suspension and termination of participation.

5. Revision History

Revision Date	Revision Type*	Author(s)	Revision Rationale, Description	Approved by
April 4, 2012	New	Hawai'i HIE	Initial version of policy	Christine Sakuda
July 15, 2013	Amendment	Legal/Policy Committee (policy sub-committee)	Content and technical-writing edits, policy identification number revision	Hawai'i HIE Board of Directors
Oct. 21, 2015	Amendment	Legal/Policy Committee	Table of contents and section numbering added; conversion of process details into procedures, existing definitions and policy sections edited to reflect current Health eNet services and operations	Hawai'i HIE Board of Directors
July 14, 2016	Amendment	Legal/Policy Committee	Edits to subsection 4.1.1 and Appendix A	

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

Appendix A

(Revised July 18, 2017)

This appendix is for reference only. It must be read in conjunction with the applicable policy, HEN-003, *Participating Entity Registration and Compliance Requirements*.

Availability of Health eNet Service Lines by Entity Type

X = Service line available for use by this entity type

HIPAA Covered Entities (i.e. healthcare providers, health plans)	Community Health Record	Referrals and Direct Secure Messaging	Image Sharing Services	Point-to-Point Conduits
Ambulatory surgery center	X	X	X	X
Community health center	X	X	X	X
Diagnostic and treatment center	X	X	X	X
Emergency medical services (EMS)	X	X	X	X
Health plan/insurer (including self-funded plan) – for treatment and care coordination only	X	X	X	X
Home health agency	X	X	X	X
Hospice	X	X	X	X
Hospital, including critical access hospital (CAH)	X	X	X	X
Individual state-licensed provider practice – led by: a doctor of medicine (MD), doctor of osteopathy (DO), doctor of podiatric medicine (DPM), advanced practice registered nurse (APRN), dentists (DDS, DMD), doctor of optometry (OD), or clinical psychologists (PhD, PsyD)	X	X	X	X
Individual state-licensed provider practice – led by: a doctor of chiropractic (DC), doctor of physical therapy (DPT), occupational therapist (OT), speech-language pathologist (SLP), certified orthotist (CO)	X	X	X	X
Laboratory	X	X		X
Nursing home	X	X	X	X
Pharmacy	X	X		X
Public health direct care provider	X	X	X	X
Radiology group	X	X	X	X
Urgent care center	X	X	X	X
Federally funded alcohol and drug treatment program (42 CFR Part 2) covered entity	X ¹	X ²		
Other third-party recipient of PHI (e.g. patient educator) ³	X	X		X

¹ CHR query only, no contribution to the CHR

² Direct Secure Messaging only, no Referral services

³ Must be approved on a case-by-case basis

Other Entities (not HIPAA covered entities, but permitted to receive PHI by and in compliance with HIPAA and other applicable laws)	Community Health Record	Referrals and Direct Secure Messaging	Image Sharing Services	Point-to-Point Conduits
Hawaii State Hospital (Kaneohe, Hawaii)	X	X	X	X
Individual state-licensed provider practice – led by: a doctor of medicine (MD), doctor of osteopathy (DO), doctor of podiatric medicine (DPM), advanced practice registered nurse (APRN), dentists (DDS, DMD), doctor of optometry (OD), or clinical psychologists (PhD, PsyD)	X	X	X	X
Individual state-licensed provider practice – led by: a doctor of chiropractic (DC), doctor of physical therapy (DPT), occupational therapist (OT), speech-language pathologist (SLP), or certified orthotist (CO)		X	X	
Business associate of healthcare provider or health plan		X		X
Business associate subcontractor		X		X
Public health authority (i.e. public health agency or entity operating under the authority of a public health agency, e.g. a cancer registry) ^{1, 2}	X	X		X
Other third-party recipient of PHI (e.g. health data organization, patient educator) ²		X		X

¹ Public health agency access upon “breaking glass”

² Must be approved on a case-by-case basis

Other Entities (not HIPAA covered entities, but permitted to receive PHI by and in compliance with HIPAA and other applicable laws)	Community Health Record	Referrals and Direct Secure Messaging	Image Sharing Services	Point-to-Point Conduits
Hawaii State Hospital (Kaneohe, Hawaii)	X	X	X	X
Individual state-licensed provider practice – led by: a doctor of medicine (MD), doctor of osteopathy (DO), doctor of podiatric medicine (DPM), advanced practice registered nurse (APRN), dentists (DDS, DMD), doctor of optometry (OD), or clinical psychologists (PhD, PsyD)	X	X	X	X
Individual state-licensed provider practice – led by: a doctor of chiropractic (DC), doctor of physical therapy (DPT), occupational therapist (OT), speech-language pathologist (SLP), or certified orthotist (CO)		X	X	
Business associate of healthcare provider or health plan		X		X
Business associate subcontractor		X		X
Public health authority (i.e. public health agency or entity operating under the authority of a public health agency, e.g. a cancer registry)		X		X
Other third-party recipient of PHI (e.g. health data organization, patient educator) ¹		X		X

¹ Must be approved on a case-by-case basis

Appendix B (Revised June 20, 2017)

Required Documentation by Entity Type and Health eNet Service Line for Participation Registrants

		Required at the Time Registration for Participation Is Submitted to Hawai'i HIE									Required Upon Hawai'i HIE's Acceptance of Registrant							
Registrant's Entity / Organization Type	Health eNet Service Line	Registration for Participation Business License (1)			BA Agreement with Another Participant (2)		BA Agreement Between BA and Subcontractor		State of Hawai'i Provider or Health Insurer License		End User Software Licenses/Agreements (3)		Data Specifications Between Participants (4)		Data Sharing / Participation Agreement Between Participant and Hawai'i HIE		BA Agreement Between Participant and Hawai'i HIE	
Healthcare provider	CHR, Imaging (5)	Y	A	N/A	N/A	A*	A - If Contributor	N/A	N/A	Y	Y							
	Direct, Referral	Y	A	A - Depends on purpose	N/A	A*	N/A	N/A	A - Depends on Purpose	Y	Y							
	Conduit	Y	A	A - Depends on purpose	N/A	A*	N/A	Y	A - Depends on Purpose	Y	Only if data manipulated by Hawai'i HIE							
Health plan/insurer	CHR	Y	A	A - For Treatment Only (6)	A - For Treatment Only (6)	A	A - If Contributor	N/A	N/A	Y	Y							
	Direct	Y	A	A - Depends on purpose	A - Depends on purpose	A	N/A	N/A	A - Depends on Purpose	Y	Y							
	Conduit	Y	A	A - Depends on purpose	A - Depends on purpose	A	N/A	Y	A - Depends on Purpose	Y	Only if data manipulated by Hawai'i HIE							
Business associate of healthcare provider or health plan	CHR	N	N	N	N	N	N	N	N	N	N							
	Direct	Y	A	A	N/A	A - Depends on entity	N/A	N/A	A - Depends on purpose	Y	N/A							
	Conduit	Y	A	A	N/A	A - Depends on entity	N/A	Y	A - Depends on purpose	Y	N/A							
Business associate subcontractor	CHR	N	N	N	N	N	N	N	N	N	N							
	Direct	Y	A	N/A	A	A - Depends on entity	N/A	N/A	A - Depends on purpose	Y	N/A							
	Conduit	Y	A	N/A	A	A - Depends on entity	N/A	Y	A - Depends on purpose	Y	N/A							
Public health authority	CHR	N	N	N	N	N	N	N	N	N	N							
	Direct	Y	A - If not a public health agency	A - Depends on purpose	N/A	N/A	N/A	N/A	A - If legal but not expressly authorized under law	Y	N/A							
	Conduit	Y	A - If not a public health agency	A - Depends on purpose	N/A	N/A	N/A	Y	A - If legal but not expressly authorized under law	Y	N/A							
Other third-party recipient of PHI	CHR	N	N	N	N	N	N	N	N	N	N							
	Direct	Y	A - Depends on entity	A - Depends on purpose	N/A	A - Depends on entity	N/A	N/A	A - Depends on purpose	Y	N/A							
	Conduit	Y	A - Depends on entity	A - Depends on purpose	N/A	A - Depends on entity	N/A	Y	A - Depends on purpose	Y	N/A							

Legend:

- (1) Business license for the geographical legal jurisdiction where the registrant conducts business. In the State of Hawaii, this is a general excise tax license.
 - (2) If registrant and intended recipient of PHI are both HIPAA covered entities, or a covered entity and a public health authority (or a third party, such as a registry, receiving PHI under a public health agency's authority), then a BA agreement is not required. If registrant is a covered entity and intended recipient is a business associate, and both are governmental entities, then a memo of understanding or other arrangement provided for in law that meets BA agreement specifications will address the
 - (3) Registrant must have a valid end-user license/agreement for the EHR or other system registrant will use to contribute data to the Health eNet Community Health Record.
 - (4) Registrant may be required to have a data trust agreement with an intended recipient, e.g. a data use agreement for transmitting limited data sets of PHI per HIPAA or data sharing agreement (or similar contract) as part of a contractual relationship between the contributor and recipient.
 - (5) Registrant must review this policy's "Types of Entities Allowed to Register for Participation" sub-section to determine if Health eNet Community Health Record and Image Sharing Services are available for the applicant's entity type.
 - (6) A health plan, and its business associates and subcontractors, shall not access or obtain PHI for which disclosure to health plans is prohibited by federal or state laws.
- Y **Yes.** Registrant must submit this document to the Hawai'i HIE.
- A **Attestation.** Registrant must submit this document to the Hawai'i HIE or provide a written attestation to the Hawai'i HIE that the applicant possesses this document.
- N **Not Available.** This document is not required since this Health eNet service line is not available to this type of registrant.
- N/A **Not Applicable.** This document does not apply to this type of registrant for use of this Health eNet service line.
- * VA provider may attest to unrestricted license.