Accountability & Oversight for HIE in Oregon

Draft Proposal

Accountability & Oversight

The Accreditation Program will fit into a larger system of Accountability & Oversight for HIE in Oregon. This larger system has three components: 1) standards to which various HIE participants will be held, 2) mechanisms for monitoring compliance with those standards, and 3) enforcement mechanisms to resolve non-compliance. The Accreditation Program will serve as the monitoring mechanism to ensure that certain participants, namely those providing or facilitating exchange services, are complying with the standards that apply to their function. These participants include local HIOs, health information service providers (HISPs), and large health/hospital systems. It does not include individual or small provider offices, clinics, or single hospitals.

There will, however, be a set of standards and monitoring mechanisms in place to ensure that these smaller entities comply with technical, privacy, and security standards that are critical for secure and effective HIE. All participants in HIE, regardless of size or function, will be subject to a review/assessment process, and will have to supply certain information for review by the State/SDE. This information will vary based on what "tier" the participant falls in. Participants would have to go through this review process as part of "pre-qualification" for the provider directory registration process and to receive a state-issued digital certificate to participate in HIE.

Tiered Accountability & Oversight System

1. **Accreditation** – Most rigorous process. Requires ENHAC or other type of national/industry accreditation in addition to Oregon-specific criteria. Could be public hearings due to scope of the entity. Audit by third-party with review by the state/SDE as part of process. Penalties and/or punitive measures for breach or mishandling of information. (See more details below.)
    - **Examples of entities that fit into this tier**: HIO, HISP, major health system or health plan

2. **Compliance** – Voluntary ENHAC (if applicable) and audit by third-party (lighter-weight audit than Accreditation). Penalties and/or punitive measures for breach or mishandling of information.
    - **Examples of entities that fit into this tier**: Large unaffiliated physician practice/clinic, single hospital system

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3. **Registration** – Process of self-attestation of best practices for information security and HIPAA/other compliance and regular auditing. Penalties and/or punitive measures for breach or mishandling of information.
    - **Examples of entities that fit into this tier**: Small physician practice (<3 providers), county public health organizations

4. **Waiver** – Process of self-attestation of best practices for information security and HIPAA/other compliance. Penalties and/or other punitive measures for breach or mishandling of information.
    - **Examples of entities that fit into this tier**: Single physician practice, physical therapists, dentists

Public Approach

1. All application materials are public – the review process will be public for the Accreditation Program only.
2. All results of review/assessment process are public – upon approval, application materials are made public
3. Appeals of the result/ruling are public hearings/meetings

Result of Approval (applies to all tiers)

1. Upon approval, entity is listed in the appropriate provider directory.
2. Entity purchases X.509 digital certificate. They may already have this in which case, they would proceed to step 3.
3. State/SDE signs X.509 digital certificate.
4. Entity can now participate in statewide HIE.

Frequency of Review or Renewal

On a regular and scheduled basis, an entity's approved/accredited status would be up for review. The review process may be anything from another self-attestation to a full audit.

Detailed Proposal for HIE Accreditation Program

There are two primary motivations and goals behind establishing Oregon's HIE Accreditation Program. First, it is critical to ensure that all entities providing or facilitating exchange services are held to the same standards in terms of protecting the privacy and security of protected health information (PHI). The HIPAA Security Rule specifies that entities must develop policies and procedures to protect the confidentiality, integrity, and availability of electronic PHI, but

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does not specify what those policies and procedures should be, nor does it have any systematic validation mechanisms in place to ensure that entities do, in fact, have the appropriate policies and procedures in place. Through Oregon's HIE Accreditation Program, mechanisms for affirmatively validating the existence and appropriateness of these policies and procedures, and for enforcing them when entities are found to be non-compliant, will be established.

A second driver behind the Accreditation Program is to ensure interoperability and participation in statewide HIE. Oregon's approach to statewide exchange is a federated model, which relies to a great extent on the HIE activities and efforts of the local health information exchange organizations (HIOs). For statewide HIE to thrive in Oregon, the local HIOs will not only need to facilitate exchange within their own communities, they will also need to communicate with one another, and with the statewide SDE. Oregon's HIE Accreditation Program will serve to ensure that the necessary technical standards, policies, and procedures are in place to facilitate exchange across HIOs and with the SDE.

The Accreditation Subcommittee, HIO Executive Panel and staff will work together to develop a proposal to bring to HITOC at the January 20th meeting. The following are key decision points that provide the framework for the HIE Accreditation Program:

1. Self-assessment process to pilot standards
2. Definition of entities that require accreditation
3. Definition of transaction type that requires accreditation
4. Accreditation process
5. State Support
6. EHNAC standards
7. State-specific standards
8. Enforcement

Self-assessment
Members of the HIO Executive Panel have already discussed going through a self-assessment process during 2011. It will be critical to identify 2 – 3 entities to pilot the draft program in early 2011. If there are state funds available to help support that effort, development of an RFP should be started immediately. Jefferson HIE and OCHIN have indicated some interest/willingness to be early participants in the self-assessment/pilot effort.

The Accreditation Program will need to go through several developmental phases to help ensure the successful launch of HIE in Oregon, to level the playing field so that local organizations and national entities are held to appropriate standards and to maintain the confidence of Oregonians in HIE.

Definition of the entities that will be accredited
All Health Information Organizations (HIOs), Health Information Service Providers (HISPs), community health data/network partnerships and other groups that promote data sharing, including the management of security and transport for directed exchange across multiple,

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independent stakeholders, whether using one platform, multiple platforms, or a vendor solution (for example, Epic CareEverywhere).

1. **HIO:** the entity provides all electronic capabilities for the transmission of clinical transactions necessary for Meaningful Use of electronic health records
2. **HISP:** The term Health Information Service Provider (HISP) has been used by the Direct Project both to describe a function (the management of security and transport for directed exchange) and an organizational model (an organization that performs HISP functions on behalf of the sending or receiving organization or individual).

Transaction types to be accredited
Organizations transmitting either clinical or administrative data will eventually need to be accredited. The initial focus in 2011 – 2012 will be those organizations handling clinical data, focusing on having the systems in place for providers to meet Stage 1 meaningful use. The Accreditation Program will evolve in concert with the evolving stages of meaningful use requirements, so that, by 2013, those organizations transmitting administrative data will also be included in the Accreditation process.

Accreditation process
After an organization has conducted a self-assessment, documentation will be submitted to the state. The Accreditation Program staff will review the materials and flag any areas of concern and return those to the organization. The organization will be given some time to respond (i.e., 30 days) and provide additional information. At the end of that time period, a public hearing will be held where the material will be reviewed and discussed, with a goal of rectifying any issues.

State support
Smaller organizations and non-profits could be provided with some technical assistance by the Accreditation Program staff to help them through the accreditation process.

Accreditation will need to be renewed biennially. Pricing still needs to be determined, but the possibility of several tiers should be considered for different sizes of organizations.

EHNAC standards
Oregon will use EHNAC standards as a baseline.

If an organization is EHNAC accredited, the state will recognize that accreditation and the Oregon HIE Accreditation Program will review any Oregon-specific standards and hold a public hearing.

If an organization is not EHNAC accredited, then the organization will need to go through a complete self-assessment, review and public hearing process.

State-specific standards
Oregon-specific standards should be considered and might include:

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- Reporting requirements around financial sustainability, including a rate plan specifying fee structures
- Public health/quality improvement reporting to meet Oregon's health reform goals Connecting to NHIN (phased in over time)

Enforcement:
Possible enforcement mechanisms could include:

- Suspension or revocation of accredited status and/or digital certificate
- Possible financial penalties for violation of statute or rule related to HIE services
- Requirement that HIOs report breach to the state, perhaps whenever the media and federal Department of Health and Human Services are notified under HIPAA

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