

**MINUTES OF THE MAY 31, 2012 MEETING
OF THE REGIONAL HIE WORKGROUP OF THE GOVERNING
BOARD OF THE ILLINOIS HEALTH INFORMATION EXCHANGE
AUTHORITY**

The Regional HIE Workgroup (“Workgroup”) of the Board of Directors (“Board”) of the Illinois Health Information Exchange Authority (“Authority”), pursuant to notice duly given, held a meeting at 2:30 p.m. on May 31, 2012 at the James R. Thompson Center, 100 W. Randolph St., Chicago, Illinois 60601, with a telephone conference call capability.

<p><u>Appointed Workgroup Members Present:</u> Dr. Cheryl Whitaker Dr. Nancy Newby (by phone)</p>	<p><u>OHIT Staff Present:</u> Laura Zaremba, Mark Chudzinski, Ivan Handler, Bukola Oni-Fatoki, Mary McGinnis, Saroni Lasker, Sarah Nelson, Krysta Heaney (by phone)</p>
<p><u>Appointed Workgroup Members Absent:</u> Mr. David Holland</p>	
<p><u>Invited Guests Present:</u> Terri Jacobsen, Metro Chicago Healthcare Crystal VanDeventer, LLHIE/ILHEP David Miller, CIHIE Charles Cox, MCHC Peter Ingram, Sinai Health System/MC HIE Steven Gravely, Troutman Sanders LLP Gail Amundson, Quality Quest for Health/CIHIE</p>	<p><u>Invited Guests Present by Phone:</u> Dr. Tom Mikkelson, ILHEP Mary Ring, ICAHN Steve Lawrence, LLHIE, ILHEP Jay McCutcheon, LLHIE Roger Crook, NIHIE Pat Schou, ICAHN Roger Holloway, Northern Illinois University/NIHIE</p>

Call to Order and Roll Call

Dr. Cheryl Whitaker, the Board Chair, welcomed the appointed members of the Workgroup as well as the invited guests. Mr. Chudzinski, Secretary to the Board, confirmed the presence of the participants noted above.

Approval of Minutes

Crystal VanDeventer noted the correction of “IHEP” following her name to “ILHEP”. The minutes of the Workgroup meeting on April 11, 2012 were approved.

Progress on Direct Secure Messaging and CCD/CCR Exchange

Mrs. Laura Zaremba advised the Workgroup that pursuant to the Federal grant requirements, ILHIE has to report messaging implementation metrics to the ONC. ILHIE only has data for ILHIE Direct Secure Messaging Exchange (“push”) messaging and therefore would like to incorporate regional HIEs Direct protocol messaging data in its

report. This incorporation of additional data will promote the success and progress of the Direct protocol messaging system.

Mr. Peter Ingram inquired as to how to represent to the ONC in understandable terms patient queries done through CCD, which are automatic requests. After Mrs. Zaremba opened the floor for suggestions, Mr. Ingram suggested documenting the number of queries as the metric.

Process and Timeline of Connecting HIEs

Mr. Ivan Handler explained in general terms what it means to connect into the ILHIE through the process of “on-boarding”. After a team of participants is established (this team can include entities such as OHIT, an HIE, whichever tech vendor the HIE is using, etc.) a Master Patient Index (MPI) must be created. The MPI is crucial to the development because without it, ILHIE will not know from where to “pull” the records. The second step is to build a Provider Information Directory (PID) of all the providers in the State, and perhaps any other states that serve people of Illinois. After the MPI and the PID are functioning, ILHIE wants to build a connection to its record locator system so participants can start doing queries.

Mrs. Terri Jacobsen and Mr. Peter Ingram discussed Tennessee’s “CHIME” program and inquired as to whether it would be useful for Illinois. Specifically, Tennessee is planning to create a CCD out of Medicaid claim data. In essence, this would populate a CCD that can be used for provider queries. Mr. Handler explained that ILHIE is not opposed to this idea. Tennessee’s CCD strategy is not impossible, but currently, ILHIE is trying to bring a new MMIS onboard. Although claims data are not the same as clinical data, and new legal questions arise, Tennessee’s CCD strategy is worth pursuing.

Mr. Peter Ingram inquired about data use agreements, stating that a major worry is the possibility of an unsolicited disclosure of patient information. Specifically, he wondered if there is any legal requirement that the State be supplied with that patient information. Is there an obligation on the part of the providers to report to the MPI? Does every patient get to decide if they participate? Lastly, does this fall into the business associate agreement rubric under HIPAA? Mr. Chudzinski replied that HIEs are considered business associates. Mr. Steven Gravely further commented that patients have to be given meaningful choice, which can be opt-in or opt-out.

Progress on Consent Management

Starting off the discussion, Mr. Handler indicated that ILHIE is determined to have service by the end of the year that everyone will be able to use. Ideally, ILHIE would like to implement a consent system that is uniform throughout the State, but the hard part is in the details.

First, a system for handling patient sensitive information needs to be established. A starting point is to make a definitive list of what falls under these five categories of sensitive

information (HIV, mental health, substance abuse, clinical, and genetic testing). Then once there is a definitive list in place, there needs to be a rubric that addresses where a person falls in terms of the type of sensitive information, whether they have consented, and then what information must accordingly be suppressed. To help organize this, Mr. Handler requested that the HIEs send him the consent forms they use so he can start going through the inconsistencies and eventually establish a single set of metadata that describes consent.

Multiple participants raised concerns about streamlining consent at the State level when all hospitals and physicians have their own consent forms. Because the HIEs are all doing different things, Mr. David Miller suggested having a set of established procedures that are agreed upon and manageable. Mr. Miller's idea is plausible, but regardless, Mr. Handler would like to see the consent forms currently used by the HIEs.

Currently, consent is managed at the point of care, but Mr. Handler envisions moving consent up to the State-level HIE to be managed. It is important to note that this cannot be done now, but the concept of letting the State-level HIE receive the unfiltered data and then filter it is in the process of being developed. This model raised concerns for most participants because it is so different from the current state of consent management, and therefore should be discussed again at a separate meeting scheduled for a later date.

The participants discussed next steps. The participants decided that Mr. Chudzinski would meet with the regional HIEs to obtain their input in the work plan and deliberations of the Board's Data Security and Privacy Committee. The regional HIEs should review OHIT's May 8, 2012 reply regarding the eight key privacy and security domains proposed by the federal Department of Health and Human Services, Office of the National Coordinator for Health Information Technology ("ONC") in its Program Information Notice ("PIN") Number 003, issued on March 22, 2012 to the HIE cooperative grant program recipients, including the State of Illinois. Similar privacy and security concerns now need to be addressed in relation to the Request for Information ("RFI") issued by the ONC on May 15, 2012 (77 Fed. Reg. 28543) regarding "Nationwide Health Information Network: Conditions for Trusted Exchange" ("NwHIN RFI"). OHIT should obtain from the regional HIEs an appreciation of the different stakeholder positions that need advocating and start establishing the corresponding testimony. The participants agreed that the regional HIEs will send their consent forms, documents, or descriptions to Mr. Handler, but that he simultaneously will write out his "vision" and send it to the panel members for further discussion.

HIE Regulatory Update

The ONC gave Program Information Notice directions on how it wants its grant money spent. PIN-003 sets out 23 elements that ONC "recommends" all HIEs "should" have with respect to HIE privacy and security policies. On May 8, 2012, OHIT submitted to ONC its Strategic and Operational Plan as well as its reply comments to PIN-003

A. OHIT Initial Assessment of ILHIE Implementation

OHIT solicited and was grateful for comments from regional HIEs and incorporated them into its reply to ONC. OHIT's reply began with a statement that whichever policy is adopted, it has to involve a balancing of 16 interests. Such interests include, but are not limited to, the extent of benefit to the majority of patients; the extent of additional effort and cost to the HIEs, providers, and HIE users; encouraging the coordination of care, reduction of medical treatment errors, and improvement of healthcare and patient safety; and avoiding unnecessary duplication, increasing efficiency, and reducing healthcare system costs.

The ONC guidance under the domains was reviewed. Based on these designations, OHIT replied to ONC that nine of the listed elements were "reasonable," seven of the elements were "challenging," and seven of the elements were "futuristic."

B. IL Addressing the PIN-003 "Gap"

OHIT replied to ONC that the enabling statute of ILHIE's Authority reflects Illinois' commitment to the protection of patient privacy, patient data privacy and security policies, but details remain to be considered and adopted by the Authority and the Illinois General Assembly. In addition, OHIT responded that Illinois does have necessary procedures and mechanisms in place to make the needed policies and will be pursuing that in the next 12 months.

C. Federal NwHIN Governance RFI

In 2004, ONC issued an RFI to begin discussing the nationwide HIE ("NHIN", now "NwHIN"). At that time, the NHIN was considered a network of networks and involved a federated approach. By contrast, the "NwHIN" has evolved into a multi-layer and multi-user internet connectivity system comprised of "NwHIN Direct" and "NwHIN Connect." At a basic level, the NwHIN is a virtual network that uses a common set of standards to allow transmission among members of a closed user group. Currently, there are 24 public and private members and 15 more entities with pending membership.

In preparation for the expansion of NwHIN, ONC issued the NwHIN RFI on May 15, 2012. This RFI is simply an information gathering exercise as ONC does not have regulations ready for implementation. ONC has asked that all replies be submitted by June 15, 2012.

The main challenge confronting the ONC is patient trust. The use of a "directed" electronic exchange (provider to provider "push") raises limited privacy and security challenges because the sender and recipient are both known parties, there is a relatively small pool of PHI data exposed to potential breach, and the transmitted data are encrypted. By contrast, query-based electronic exchanges ("pull") raise greater privacy and security challenges because they expose a much larger pool of PHI data to potential risk to a broader potential number of persons.

ONC has established two new acronyms relevant to the implementation of NwHIN. First, the "NVE" refers to a "Network Validated Entity" that has become an admitted member.

Second, the “CTEs” refer to “Conditions for Trusted Exchange” that comprise the admission criteria.

1. NwHIN Membership Criteria for NVEs

To become a “NVE” of the closed user group, the entity must first have its identity confirmed. Next, the entity must be granted security credentials (encryption keys). Last, the entity must agree to the terms of use (essentially DURSA), which outlines 1) safeguards (security policies and procedures), 2) interoperability (technical standard for data exchange and integration), and 3) business practices (operational and financial).

Safeguards—Security Policies and Procedures

There are currently ten safeguard “CTEs” required for membership admission:

- NVEs must comply with 45 CFR §§164.308, 164.310, 164.312, and 164.316 (HIPAA “Security Rules”) as if they were a covered entity and must treat all implementation specifications within 45 CFR §§164.308, 164.310, and 164.312, as required
- NVEs must only facilitate EHI exchange for parties it has authenticated and authorized—directly or indirectly
- NVEs must provide individuals with a meaningful choice as to whether their IIHI may be exchanged by the NVE

The RFI specifies three potential exceptions to providing individuals with meaningful choice. The exceptions are (1) medical treatment, (2) disclosures required by law, and (3) an NVE is solely a transmission conduit. Mr. Chudzinski elaborated that the inclusion of an exception for medical treatment is significant because in PIN-003 the ONC essentially overturned HIPAA by disallowing a reliance on the treatment-payment-healthcare operations (“T-P-O”) exception for PHI disclosure without patient authorization, instead requiring NVEs to obtain patient opt-in or opt-out. Now, the RFI admits medical treatment (“T” of the “T-P-O”) as an exception.

- NVEs must only exchange encrypted IIHI
- NVEs must make notice of their data practices publically available. Notice must include why IIHI is collected, how it is used, and to whom and for what purpose it is disclosed
- NVEs must not use or disclose de-identified health information for any commercial purpose
- NVEs must operate 24 hours a day, 7 days a week (with high availability)
- If an NVE assembles or aggregates health information that results in a unique set of IIHI, then it must provide individuals electronic access to their unique IIHI
- If an NVE assembles or aggregates health information that results in a unique set of IIHI, then it must provide individuals with the right to request a correction and or annotation to the unique set of IIHI
- NVEs must have the means to verify that providers requesting patient health information through a query and response model have or are in the process of establishing a treatment relationship with that individual.

Interoperability—technical standards for data exchange and integration

- NVEs must be able to facilitate “planned exchange” when:
 - (1) the sender and receiver are known
 - (2) the exchange occurs at the patient’s direction, i.e. Direct “push”
- NVEs must follow required standards for establishing and discovering digital certificates
- NVEs must have the ability to verify and match the subject of a message, including the ability to locate a potential source of available information for a specific subject

Business Practices—operational and financial

- NVEs must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE
- NVEs must provide open access to the directory services they provide to enable planned electronic exchange
- NVEs must report on user and transaction volumes for validated services—at the aggregate level such that the data are not identifiable.

Mr. Chudzinski suggested that the first and second business practices requirements raise serious questions of NVE sustainability, in the event NVE entities providing directory services may not charge to compensate for the expense of managing and maintaining an expensive directory.

2. Anticipated NVEs & Resulting Eligibility Criteria

ONC anticipates that eligible entities may include, but not be limited to, EHR developers such as Epic Systems, Axolotl, and SAIC; integrated delivery networks such as Marshfield clinic and Kaiser Permanente; regional, state, and local or specialty-based health information exchanges such as MedVirginia; health information service providers such as Emdeon; and State and Federal agencies such as SSA, DoD, and DVA. Further, it has been suggested that NVE status may become a necessary qualification for obtaining Federal contracts from programs that use electronic exchanges.

ONC has provided a list of criteria that it anticipates NVEs will be required to satisfy. Such criteria include solvency and financial requirements, financial disclosure filing, surety bonds or other forms of financial security, overall resources and experience (likely a showing of one year minimum), effective and efficient administration as evidenced by serving a sufficient number of providers, and no prior bad acts or disqualifications. ONC has postulated that other potential criteria may include NVEs demonstrating a “valid” purpose for exchange, 501(c)(3) tax status, and the segregation of NVE validated services from other services the NVE provides.

In the ensuing discussion, it was acknowledged that the NwHIN RFI proposes future policies that would potentially affect the ILHIE and regional HIEs in Illinois, and that a response by the Authority on behalf of stakeholders in Illinois would be appropriate.

APPROVED 4/3/13

Public Comment

There were no comments offered from the public.

Adjournment

The meeting was adjourned at 4:50 p.m.

Minutes submitted by Sarah Nelson