

**Illinois Health Information Exchange Legal Task Force  
Genetic Testing Workgroup Meeting  
February 8, 2011  
Meeting Minutes**

In-Person Attendees:

Mary Lucie, Northwestern Memorial Hospital  
Richard Wagner, Wagner Consulting, LLC

Office of Health Information Technology:

Mark Chudzinski, General Counsel  
Lindsay Kessler, Intern  
Vaughn Ganiyu, Intern

Attended by Phone:

Maia Thiagarajan, Ingalls Health System  
Claudia Nash, Illinois Department of Public Health  
Kelly Carroll, St. Louis University  
Maureen Smith, Northwestern University  
Cathy Wicklund, Northwestern University  
Monique Anawis, Weiss Memorial Hospital  
Elizabeth Payton, Illinois Department of Public Health  
Anne Mahalik, Illinois Department of Public Health

**Introduction:**

Mark Chudzinski opened the meeting at 3:30pm, hosted by OHIT at the State of Illinois J.R. Thompson Center in Downtown Chicago, with a video conference link to the State of Illinois Bloom Building in Springfield, and a telephone conference call-in number. It was noted that notice of the meeting and the agenda were posted on the OHIT website and at the Chicago meeting location no later than 48 hours prior to the meeting. Roll was taken, and the ability of those attending by telephone to hear and participate was confirmed.

The overall purpose of the meeting was stated: to review the matrix that was sent out to the workgroup prior to the meeting. This matrix outlined the Illinois Genetic Information Privacy Act (GIPA) Illinois Genetic Counselor Licensing Act (GCLA), Illinois Newborn Metabolic Screening Act, Federal Genetic Information Nondiscrimination Act (GINA) and proposed changes to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. It was noted that this is a draft for discussion purposes to further the workgroup's analysis of Illinois and Federal laws to determine barriers to implementing the Health Information Exchange (HIE) in Illinois. It was also noted that this review of the draft of the matrix was intended to obtain suggestions, comments, and edits by the workgroup.

Mary Lucie posed a question to the workgroup as to what would be the best way to get through the questions. It was discussed at that time as well as at the end of the meeting whether the larger workgroup could be divided into groups based on statutes or the entire workgroup could walk through the analysis addressing one question at a time. (The group decided after the meeting to follow through with dividing into subgroups based on the two Illinois statutes: (i) the Genetic Information Privacy Act (“GIPA”); and (ii) the Genetic Counselor Licensing Act (“GCLA”).) Maia Thiagarajan shared that this focused review was based on the fact that Illinois law would most likely preempt Federal law on these issues because it is more stringent than Federal law. Also, it was noted that GCLA mentions provisions from the Illinois Mental Health and Developmental Disabilities Code which will overlap with the work being done by another workgroup of the Illinois Health Information Exchange taskforce. Mark confirmed that overlap issues would be a topic of conversation at the next Executive Committee Meeting.

**Matrix Review:**

The workgroup looked at the draft matrix document as a large group. The far left column stated questions for consideration with each of the respective statutes. The first row examined different terminology as defined by specific statutory language. These definitional variations were emphasized throughout the remainder of the analyses.

The workgroup began its discussions focusing on page 5 of the matrix, dealing with the question of disclosure for treatment purposes under GIPA. Illinois law allows an entity to disclose genetic information for the purpose of treatment to the HIE with the requisite consent. Mark asked the workgroup to consider if this express exception for treatment, similar to the HIPAA standards, was sufficient for data security in the HIE. Should the law expand the number of permitted disclosures? Suggestions included forwarding data to certified HIEs aside from those at the state level (considering the HIEs at the local level first).

Mark noted that HIE is a fluid and evolving concept and is currently not running at the state or local level. However, the purpose of HIE is for treatment and improving patient care, along with the aspects of public health and patient information that will be used towards the research and quality/cost control of treatment. Further, since the HIE is not yet developed, patients need comfort in the statute that says forwarding information to the HIE is recognized as a permitted exception under GIPA. Thoughts were expressed about the potential duty for each entity that provides information to the HIE and the heightened duty to protect sensitive patient health information.

The workgroup continued with discussion, recognizing that the Federal GINA statute was much more complicated and may need to be separated into Title I and Title II for purposes of the matrix.

## **Practitioner Viewpoints**

Members of the group shared the perspective of genetic counselors with respect to confidentiality of genetic tests and counseling records. It was explained that Genetic Counselors have been traditionally very conservative and genetic information has been separated from a patient's medical record. A member pointed out that the President's Council of Advisors on Science and Technology (PCAST) and State laws protect certain types of information which has unintended consequences for practitioners. Often, this results in the conservative policy mentioned above and the sequestering of information, which creates problems for the clinical community in having to rely on "Swiss cheese" medical records. What should practitioners do when certain information is left out of a patient's record?

Other members shared their thoughts that the most conservative approach would be to ask patients to specifically authorize the release of their genetic information. In addition, while genetic counselors seem to be getting better with incorporating the results of genetic tests into a patient's overall medical record, it was clear that this could vary from one institution to another. Usually genetic counselors are willing to share these results with other doctors but less likely to share this information another institution without a patient's express authorization.

Additionally, genetic test results are usually recorded in paper charts and rarely found in electronic form. This creates difficulties when medical professionals need to locate these results. Other barriers include formatting issues, as genetic test results are not formatted in way that's easy to put into an electronic health record (EHR). The workgroup expressed this integration problem as a large issue for the genetic counselor community.

Similarly, newborn records also presented a problem. A member described the process, where the results of newborn screening tests remain in lab report form and hospitals scan them into a patient's medical records. However, other hospitals need to manually enter these results into their institution's system, depending on the formatting of EHRs.

A member also described to the workgroup that new databases have additional capabilities but are not yet in use because of the need to work with individual hospital systems. Mark explained that the HIE is only a record locator system (RLS) and does contain patient information itself and different levels of security need to be established.

A question was raised as to whether employers should have access to this type of information. If they are acquiring this information for insurance purposes, patients may be concerned about secondary uses of genetic information. Mark clarified information provided would be limited to simply knowing the patient had testing completed; the results of these tests would remain confidential.

## **HIE Architecture and Discussion:**

The workgroup then turned their attention to further understanding the administrative and organizational components of the HIE in Illinois. A member of the group asked that due to the fact that researchers, physicians, or payers may have access to the HIE for information related to treatment, would the current security rules contemplated for the HIE, block out private genetic information. Mark explained that clinical data will likely remain with the disclosing entity behind its firewalls and that information will be passed to the state as allowed under the law. Mark further explained that the state would provide for a record locator service (RLS) along with a master patient index (MPI), which can be used in conjunction to query information pertaining to a particular patient. Mark concluded by stating that information will not be pointed to the RLS unless the information falls into one of the traditional HIPAA exceptions, such as being related to treatment, payment, or healthcare operations.

Another member raised an issue to determine whether consent is needed in the process of submitting and accessing information from the HIE and if so, at what point in time is consent required and/or should be obtained from the patient (i.e., the point of care from the provider or at the time information is queried from the HIE). Mark suggested that members of the workgroup should review empirical as well as anecdotal evidence of how big hospitals, medium size hospitals, and primary care physicians treat the consent issue.

Another member raised an issue of the characterization of the HIE and whether it is an authorized agent under GIPA. Is the HIE an authorized agent under GIPA or does the HIE's status need to be expressly set forth under the statute? Mark explained that currently under GIPA, a disclosing entity may disclose genetic information to an authorized agent or employee of a health facility that provides patient care (413 ILCS 513/30(a)(3)).

The question was asked whether the HIE would be regarded as a Business Associate under HIPAA. Mark responded in the affirmative, citing the Health Information Technology for Economic and Clinical Health Act (HITECH). Mark then offered a possible proposal to the issue by stating that information could be provided to the HIE if it is acting as an agent in conformity with the applicable Illinois statutes, but HIE's actions could be limited by a given statute's expressed exceptions.

Another member addressed the issue of whether Illinois should adopt an opt-in approach or an opt-out approach. The group briefly discussed the approaches taken by other states in regards to adopting an opt-in method or an opt-out method. Mark explained that Rhode Island adopted an opt-out approach on an all-or-nothing basis, while New York, Minnesota, Connecticut, and Hawaii adopted an opt-in approach for everything. He also stated that other states such as North Dakota defaulted to Federal law, while the practice in New Mexico is to adhere to an opt-in approach even though their laws provide for an opt-out approach. Mark stated that Illinois has not taken a position yet on whether to implement an opt-in or opt-out approach.

A member asked whether the technology is currently available to allow for genetic information to be sequestered. Mark asked the whole group to reach out to their colleagues in other states and ask them about best practices on the issue of sequestering genetic information.

Mary then asked if there are any national organizations where the workgroup could receive information related to the sequestering of genetic information. A member responded and said that the workgroup should look into an organization called the National eHealth Collaborative.

A member of the workgroup also asked if there is a thought in the clinical community as to whether genetic information needs to be classified as sensitive information. Another member asked if there are any neighboring states that have more liberal laws in regards to genetic information?

Mary then provided the workgroup with a quick recap of the main topics highlighted during the meeting.

Mary then asked the workgroup as to how the work should be divided up amongst the work group moving forward (i.e., by statute, by group, or by topic). As noted above, due to the time constraints, at the conclusion of the meeting, Mary and Maia decided that the work should be divided into two groups, where each separate group will review one of the two Illinois statutes regarding genetic information. Mary agreed to circulate an e-mail containing a sign-up sheet to all of the members, so that they may choose which subgroup they want to participate in.

### **Meeting Date**

The next meeting date was not set at this meeting.

### **Other Business/Public Comment**

There was no public comment offered in response to the chairman's invitation for public comment.

The meeting adjourned at 4:48 p.m.