

**Illinois Health Information Exchange Legal Task Force
Genetic Testing Workgroup Meeting
December 20, 2010
Meeting Minutes**

In-person Attendees:

Mary Lucie, Northwestern Memorial Hospital
Richard Wagner, Wagner Consulting, LLC
Cathy Wicklund, Northwestern University
Maureen Smith, Northwestern University

Office of Health Information Technology

Mark Chudzinski, General Counsel
Lindsay Kessler, Extern

Attended by Phone:

Maia Thiagarajan, Ingalls Health System
Kelly Carroll, St. Louis University
Lawrence Singer, Loyola Law Professor
Fran Carroll, Joint Commission
Bernadette Broccolo, McDermott Will & Emery
Kelly Carroll, St. Louis University

A. Introduction

Mark Chudzinski, General Counsel of the State of Illinois Office of Health Information Technology (OHIT) opened the meeting at 2:00 p.m., hosted by OHIT at the State of Illinois J.R. Thompson Center in Downtown Chicago, with 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.

Mark Chudzinski welcomed the meeting participants and noted that the state of Illinois is committed to the development and implementation of a statewide health information exchange (HIE) in order to: improve health outcomes, achieve better care coordination among providers, reduce medical errors, reduce health disparities, and control health care costs.

Additionally Mark Chudzinski gave an overview of OHIT and presented the goal of the HIE Legal Task Force as identifying shortcomings in Illinois laws that impede health information exchange, and proposing solutions to such shortcomings. He stated that OHIT is actively seeking the involvement of knowledgeable individuals from the private sector in providing non-binding advice with respect to the challenges presented by Illinois law for the development of health information technology in the State of Illinois. The HIT Legal Task Force will solely provide non-binding advice to OHIT, which will have exclusive authority in its absolute discretion to adopt, or reject, any such advice. (In turn, any recommendations that may be made by OHIT to the Illinois General Assembly and/or the Illinois Health Information Exchange Authority (currently in formation) (“HIE Authority”) are purely advisory, and may be accepted or rejected by such other bodies in their sole discretion.) All workgroup discussions and work product of the Task Force will be both “vendor-neutral” and “client-neutral.” The Task Force will not assist the

State of Illinois, OHIT, the Authority, or any other State of Illinois agency in reviewing, drafting, or preparing a request for proposal or request for information relating to State of Illinois procurements, or in determining whether there is a need for a contract to be entered into by the State of Illinois, OHIT, the Authority, or any other State of Illinois agency. The Task Force will not review or discuss any vendor-specific solutions that may someday be considered for procurement by the State of Illinois, OHIT, the Authority or any other State of Illinois Agency. The Task Force will not participate in the making of any regulatory or licensing decisions of the HIE Authority, or of any other State of Illinois agency.

B. Relevant Laws

Mary Lucie, Northwestern Memorial Hospital, pointed out relevant laws and materials for the workgroup's consideration when identifying possible barriers to HIE, consistencies and discrepancies with Federal law, and recommendations for future policy. These include the following:

The Genetic Information Privacy Act (410 ILCS 513/15, 40(a)) looking at both the legislative findings and intent to determine when the uses of genetic testing can be valuable to an individual, comparing it to existing authorities that regulate the use of genetic testing information and under certain disclosure conditions, and considering it in terms of public deterrence – when individuals are afraid their test results will be disclosed without their consent and/or used in a discriminatory manner. Additionally, looking at how the Genetic Information Privacy Act may serve public health initiatives by facilitating voluntary and confidential nondiscriminatory uses of genetic testing information. (410 ILCS 413/5)

As a cross reference, it would be useful to examine the uses of information derived from genetic testing, (215 ILCS 5/356v). After the effective date of this amendatory Act of 1997, an insurer must comply with the provisions of the Genetic Information Privacy Act in connection with the amendment, delivery, issuance, or renewal of, or claims for or denial of coverage under, an individual or group policy of accident and health insurance.

Other pertinent laws include the Genetic Counselor Licensing Act (225 ILCS 135/90(a),(b)), HIPAA (consider the proposed changes to the Privacy Rule that states that genetic information is protected health information and prohibits the use and disclosure of genetic information for eligibility determinations, premium calculations, applications of pre-existing condition exclusion and other activities related to health insurance or health benefits), and the Genetic Information Non-Discrimination Act of 2008 ((GINA)[Pub. L. 110-223, 122 Stat. 81 (2008)]).

Additionally, a copy of following law review and journal commentaries will be available at the next workgroup meeting and may be useful sources of information: Deborah L. McLochlin's *Whose Genetic Information is it Anyway? A Legal Analysis on the Effects that Mapping the Human Genome will have on Privacy Rights and Genetic Discrimination* and Brian M. Holt's *Genetically Defective: The Judicial Interpretation of*

the Americans with Disabilities Act Fails to Protect Against Genetic Discrimination in the Workplace.

C. Relevant materials

To additionally assist the workgroup's goals, the following resources should be considered in its analysis: Best practices in other states (i.e.: Missouri and the Missouri Health Information Exchange – another taskforce is already engaged in this process and it may be useful to consider their proposals for change), a Texas lawsuit regarding the Newborn Screening Saves Lives regulations, workgroup #5's Public Health Reporting (see pgs. 7-10 of the OHIT task force descriptions), the Secretary of SGHCJS (definition reviews available on website), OCR rules and proposed recommendations to exclude genetics, Use Case Hypotheticals, the Region 4 Collaborative Network (HERSA), and please continue to think mandatory/elective tests that might have genetic implications! Additionally, it was noted that possible overlap with the other workgroups may exist and may be called upon for additional research.

D. Workgroup Tasks

The following tasks and questions were identified for the workgroup to consider in the future: Whether the existing laws impede the implementation of HIEs? Whether there are gaps or ambiguities in existing laws that should be addressed? If genetic testing and information derived from genetic testing may be released “only to the individual tested and to persons specifically authorized,” except pursuant to a “specific written legally effective release” (410 LCS 513/15)? What are the implications for the use of HIEs for routing lab results?

Consider that according to (410 ILCS 513/30(a)), no person may disclose the identity of any person upon whom a genetic test is performed. Would a provider's forwarding of patient ID and record location data to an HIE's MPI and RLS database be prohibited? Are recipients of a disclosed data set may, in turn, “re-disclose” without obtaining the patient's consent (410 ILCS 513/35)? What implications for HIE does the arguably “granular” consent requirement impose?

Should these laws be updated to correspond to the HIPPA Privacy Rule? Should Illinois law expressly provide for a “business associate” exception? What does it mean to “de-identify” information under these laws?

Do these laws accommodate a non-paper patient consent management workflow? Do these laws accommodate the development of PHRs, and the transfer of PHI related to genetic testing and/or counseling to PHRs? Do these Illinois laws accommodate telemedicine, and access by Illinois patients and health care providers to telemedicine services? Do these laws accommodate medical research?

What are possible recommendations for adopting certification procedures for who is allowed to participate and gain access to the HIE records? Consider the opt-in vs. opt-out

debate – since Illinois is generally presumed to be an “opt-out” state while some states are “opt-in,” the OHIT should aim to promote opt-out which would include as much data as possible in the HIE (arguing that opt-in results in less data because patients don’t want to be bothered with more paperwork. Since Illinois has not decided yet, any justifications or views will help facilitate this necessary debate.

What are the secondary uses and implications of HIE? How will this affect prescriptions recommendations based on genetics? Adverse drug reactions? What about genetic research that suggests clinical quality improvements linked to specific medications? How will prevention shift uses, not just treatment? Should we write a letter of support for new report/Missouri? Team up with other states? Ultimately we need to identify existing problems within Illinois.

E. Closing Remarks and Adjournment

At the end of the Genetic Testing workgroup’s sessions, the OHIT will draft a whitepaper with recommendations to overcome barriers to HIE implementation. The timeline is as follows: until late-January/early-February, the workgroup should focus on membership and scope. The initial draft of the whitepaper is due mid-March and a second meeting time has been set at OHIT offices, 100 Randolph for Tuesday, February 8 at 3:30pm. Members may attend in person or by phone.

There was no public comment offered in response to the [chairman’s] invitation for public comment.

The Meeting adjourned at 4pm.