

**IL HIE Legal Task Force
Executive Committee Meeting
Meeting Notes
October 28, 2011**

In-person Attendees:

Bernadette Broccolo, McDermott, Will & Emery
David Carvalho, Illinois Department of Public Health
Deaton, Illinois Hospital Association
Beth Donohue, Popovits & Robinson
Laurel Fleming, Northwestern Medical Faculty Foundation

Office of Health Information Technology

Abraham Arnold, Legal Intern
Mark Chudzinski, General Counsel Mark
Michael Flanigan, Legal Intern
Melissa Tyler, Legal Intern
Kevin Yao, Legal Intern (by phone)

Attendance by Phone:

Patricia King, Swedish Covenant Hospital
Mary Lucie, Northwestern Memorial Hospital
Maria Pekar, Loyola University Health Systems
Maia Thiagarajan, Ingalls Health Systems
Marilyn Thomas, Illinois Department of Healthcare and Family Services

Bernadette Broccolo, co-chair of the Executive Committee, opened the meeting at 1:00PM hosted by Bernadette at McDermott, Will & Emery 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.

The minutes for the September 19th meeting were approved without objection.

Bernadette began by thanking all of the groups for their hard work analyzing and presenting the issues. She explained that her goal for the meeting was to look at the group reports side-by-side and determine what common themes arise from them. Then the group could focus on developing a mainstream approach to addressing the barriers the various laws present to the implementation of a health information exchange (HIE) in Illinois.

Mark Chudzinski, OHIT, explained that the timing of this meeting was optimal because the IL HIE Authority Board (Board) will be meeting December 1, 2011. At this meeting, the Board is expected to create a Privacy and Security Committee to advise the Board. He explained that this committee will likely look to the Legal Task Force for guidance. This guidance, he suggested, could be in the form of a whitepaper or other analysis.

Legislative Considerations

The group next discussed the legislative considerations that the Task Force should keep in mind in drafting its whitepaper and recommendations. It was suggested that work should begin now in order to get legislation into the Spring 2010 legislative session. The legislation will need sponsors, legislative champions, and supporters who will stand up and articulate the goals of the

legislation. It will also be important to obtain the support of stakeholder interest groups. A document or set of documents will need to be created that articulate the legislative goals and recommendations. These documents will be used to facilitate the conversations that need to take place with the above-mentioned individuals and groups.

The work product that the Legal Task Force will be creating will likely be a large and complex document. Therefore, it was suggested that simpler documents be created that address the broad public policy goals and legislative issues. These documents should describe the advantages of the HIE, e.g., it will contribute to the improvement of access to health care, quality of health care, and cost of health care. The documents should also explain why and how legislation must change to facilitate the HIE. Additionally, because of the complexity of the legal issues, the documents should be crafted in varying degree of detail. For example, one draft should be created for the various stakeholder groups and another, probably more detailed, created for the legislative staff and the drafters. These documents are a critical step in getting legislation passed and the whitepapers that the Legal Task Force creates will feed into these documents.

With regard to the discussion on legislative process, it was noted that the bill introduction session is underway in the executive branch and that the General Assembly bill introduction session ends in January. As such, the Task Force should keep in mind that the deadlines are approaching. It is possible to introduce a “shell bill” which is a bill that has no content when introduced and is amended later. A “shell bill” has pros and cons. It can be beneficial when the substance of the bill has not yet been worked out; however, a “shell bill” encourages delay for the drafters, as they end up drafting amendments last minute.

The need for legislator and stakeholder support was recognized. Along with any supporting documents, two or three easily understandable antidotes should be crafted that highlight the need for the HIE.

In the ensuing discussion, it was noted that the authority that needs to take the lead in legislative efforts is the IL HIE Authority Board and its Chairperson. The group agreed that the Legal Task Force’s function is advisory in nature, not policy making. It was noted that the Board can and should begin the policy making conversations about the broad issues now. It was noted that the lawyers of the Task Force will work on the technical issues, but the conversations on policy issues should start now before anything is decided or drafted.

Whitepaper Discussion – The Issue of Consent

Next, the Executive Committee discussed the process of drafting its whitepaper. It was determined that the threshold legal question is what kind of patient consent will be required to send health information through the HIE: (1) no consent, (2) opt-in consent, or (3) opt-out consent. It was noted that each option poses different issues for different laws.

In the ensuing discussion, the group noted that because Illinois has different consent requirements for different types of patient information, it may be advantageous to create an independent HIE statute and amend the problematic statutes to look to the HIE statutes. This could be done regardless of the model of consent Illinois adopts. It was also noted that the group should consider whether Illinois law should be amended to harmonize with HIPAA.

Mark Chudzinski explained that it is likely that federal government will soon release a set of NwHIN governance guidelines. He anticipates that these guidelines will incorporate the “Tiger Team” recommendation that all HIE require patient consent to transfer information. The group agreed these guidelines seem to preempt the HIPAA TPO (treatment, payment, operation; 45 C.F.R. 164.506) exception that allows information to be shared without consent in certain situations. It was noted that if these guidelines are adopted as amendments to HIPAA, Illinois will have to comply with them. Mark also suggested that the group consider what can be done by regulation versus statute, especially because regulations do not have to meet the same deadlines that legislation does.

Next, Mark quickly reviewed the work products that had been submitted to the Executive Committee by the workgroups. The following groups have advanced work products that are near completion: Public Health, Genetic Testing, Liability, and Behavioral Health. The General PHI, Patient Consent, and Disclosure of Labs, Prescription Drugs, and Payers Groups are still working, but are getting close to completing drafts.

The group decided that rather than have each subgroup give a report, they would continue with the analysis of the issues, specifically the consent issue. The group determined that, because the consent issue is ultimately a policy decision for the Board, its whitepaper should present the Board with all the information it needs to make this decision. It was suggested that the group create a grid that lays out the legislative changes that need to be made if either of the three consent models are chosen: opt-in consent, opt-out consent, or no consent.

In the ensuing discussion, it was noted that the Behavioral Health Workgroup whitepaper made an important observations that the definitional portion of some of the statutes may also need to be amended. This is because some the statutes are vague as to the exact patient information that is protected. For example, in the Illinois Mental Health and Developmental Disabilities Confidentiality Act (IMHDDCA, 740 ILCS 110/), the term “mental health record” is not defined. This could be problematic for the HIE because under the IMHDDCA as it is today, providers must get consent before transferring mental health records. However, if the provider is not sure whether the record is a mental health records, this could be difficult. It was noted that this ambiguity in the law is causing providers to avoid sending any hyper-confidential information to HIEs. It was determined that three types of Illinois laws need to be amended from a definitional standpoint: genetic testing, mental health, and substance abuse.

It was suggested that each work group identify definitional changes that needs to be made to the laws that they reviewed. Once the groups have identified these issues, then they should consider what changes need to be made if either of the three consent models is adopted. It was noted that not all of the laws analyzed will need to be changed in terms consent, but some will. For example, the IMHDDCA will need to be to be amended because of its prohibition on “blanket consent.” One possibility is to suggest that the IMHDDCA be amended to state that the “blanket consent” prohibition does not apply for certain HIE purposes.

The group next considered whether a privacy issue is implicated where a patient’s prescription records reveal that he or she has a certain condition. For example, a patient is on a drug that is

only used to treat HIV; therefore, the provider knows that the person is HIV positive because he or she is on the drug. The group considered whether the fact that the person is on this drug is confidential, therefore requiring special consent. It was noted that not including this information in a report could have severe negative impacts on treatment. The group also noted that in addition to prescription information, information such as medical history, assessment of violence, diagnoses, and vital signs would be beneficial for the provider to obtain from an otherwise confidential record.

In the ensuing discussion, it was suggested that, if there was a way to carve out diagnosis and medications from the consent rules, the transmission of information would become easier because there would be no need for particularized consent. This would be an important carve out because for many medications, there is a patient safety issue if the physician is not aware that the patient is taking them.

Bernadette noted that none of the above discussion should be considered proposals or recommendations. The group was simply talking through the issues.

In the ensuing discussion, the group decided that it should, in its whitepaper, explain to the Board the existing legal hurdles to operating an HIE in Illinois and provide some options for overcoming these hurdles. The group decided, as noted above, that it would also present to the Board the three consent models and the legislative changes that would need to be made to implement each model. For example, the paper may say, “we have identified three ways states have approached the consent issue: (1) opt-in consent, (2) opt-out consent and (3) no consent. We have analyzed the Illinois statutes from each approach and made note of the statutory changes that would be required to implement each policy.”

Bernadette explained that it is important that the work product presented to the Board is drafted in a way can be easily understood. Additionally, she hopes to develop as much consistency across statutes as possible.

Whitepaper: Additional Consideration

Next, the group considered other elements that would be beneficial to incorporate into an HIE statute. These include: (1) re-disclosure; (2) business associates; (3) “break the glass” emergency exception; (4) consistency with HIPAA; and (5) de-identified or limited data set.

In the ensuing discussion, the group considered whether the HIE’s would be considered a “business associate” under HIPAA (e.g. pursuant to HITECH Act §13408, embodied in proposed NPRM amendments to 45 C.F.R. 160.103). Specifically, the group discussed whether the state-level HIE could be considered a “business associate” of every health care provider. If so, the provider would be free to share information with the state-level HIE, relying on the HIE to apply the consent rules. It was noted that this could be a way for the provider to send information to the HIE without having to worry about consent, regardless of the consent scheme applied.

Additionally, the group should consider the logistics of patient consent opt-in and opt-out. Specifically, is it a question of patient consent limiting whether PHI can be placed into a

database within the HIE, or whether consent is required to retrieve the relevant PHI out of the HIE, or whether PHIC can only be transferred through the HIE (without any substantial persistence within the HIE) ? It was noted that for mandatory public health reporting and other purposes, it would be preferable for PHI data to be collected by an HIE but to have any PHI disclosure limitations imposed by a patient consent management process apply to the potential subsequent disclosure of relevant data by the HIE (rather than its initial collection).

Mark Chudzinski explained that when the Task Force presents its guidance to the Board, there are at least three additional aspects that should be included: (1) a public education component regarding the ILHIE and its uses and protection of patient PHI, (2) the creation of an institutional review board (IRB) for reviewing the proposed medical research and other secondary uses of the ILHIE patient data, and (3) an enhanced enforcement of Illinois' PHI privacy and security laws. The ILHIE would at least have to provide the protections outlined in HIPAA.

In the ensuing discussion, the group considered the Medical Patient's Rights Act (Act, 410 ILCS 50/3(d)), specifically Section 3. It was noted that this section should probably be amended because it predates HIPAA by about ten years. The group noted that this Act has been interpreted as being consistent with HIPAA, but it would be beneficial to make this explicit in the law.

The group decided that the next step is to develop a grid that compares the individual statutes from the consent perspectives. The grid will consolidate all of the information in a way that is usable. Once this grid is completed, the group will use it to draft a narrative of the issues and address some of the other issues that were brought up throughout the meeting.

In response to the chair's invitation, there were no comments offered from the general public.

Meeting adjourned at 3:50PM.