HISPC Legal Workgroup Meeting
Wednesday, September 26, 2007 10:00AM-12:00PM

In attendance:
Matt Angela, Illinois Hospital Association COMPdata
**Brian Annulis, Katten Muchin Rosenman LLP
Rob Connor, Illinois Department of Human Services
Steven Glass, Access Community Health Network
*Jeff Johnson, Illinois Dept. of Public Health (project team)
Robert Kane, Illinois State Medical Society
Kathy Karsten, Illinois Public Health Institute (project team)
Anne Mahalik, Illinois Department of Human Services
**Laura Martin, Katten Muchin Rosenman LLP
Michael Murer, Murer Consultants, Inc.
Maria Pekar, Loyola University Health System
Doug Polk, Illinois Hospital Association
Charles Sheets, Foley and Lardner
Joel Shoolin, Family Practice Medicine
Mary-Lisa Sullivan, Illinois Department of Human Services
*Marilyn Thomas, Illinois Dept. of Public Health (project team)
*Moderators
**Legal Contractors

Not present:
Julie Bryant, Northwestern Memorial Hospital
Julie Hamos, Illinois State Representative, 18th District (invited guest)
Frank Sears, Southern Illinois Healthcare
Nancy Shalowitz, Illinois Department of Healthcare and Family Services
Darryl Vandervort, Katherine Shaw Bethea Hospital

Marilyn Thomas convened the meeting at 10:05AM. She and Jeff Johnson explained the progression of work on health information exchange (HIE) to date, and Johnson gave an explanation of HISPC. Currently, the overall HISPC group has been charged with work on participation and collaboration with other states working on same issues (i.e. consent), specifically focusing on what states need to send to other states. The tasks to be completed are: 1) development of draft privacy and security policies, and 2) a draft consent form. Thomas added that the current HISPC framework is a continuation of public-private partnership, and has a fairly aggressive timeframe for completing its work. In this context, she directed the Legal work group's discussion toward what types of areas within consent that they would like to see regarding HIE.

The meeting schedule was then outlined. Legal contractors Laura Martin and Bryan Annulis will develop a working draft document and distribute it to the group by its 2nd meeting on Oct. 10. The group will discuss this draft at the 3rd meeting, Nov. 14, and will finalize it and discuss implementation and dissemination at the last meeting on Dec. 5. Thomas stressed the need to capture the issues of consumers, and balance their interests along with facilitating a more efficient

flow of information. Group members should follow up with Kathy Karsten (i.e. comments, etc.), and also track the group's work via its website (http://www.idph.state.il.us/hispc2/) and listserv.

Johnson explained the national movement on consent issues and their concomitant elements: the types of data to be exchanged between states, how to send them, and other related practicalities. The collaborative is focusing more on what needs to be exchanged and verified in order to give consent. Some states with various models for consent include:

- MN: Passed a law to set up the authorization form process, with a single uniform form for providers. The form's use is optional for patient, but required for the provider.
- IN: Has no specific authorization, but the user has to opt out of the authorization process.
- RI, MA: Both have a fairly detailed consent process.

Laura Martin and Brian Annulis explained their role in the group, and discussed challenges regarding consent. Referring to the accompanying PowerPoint presentation, Martin facilitated a discussion on some of the important considerations outlined in four propositions:

- Proposition # 1-The MC is NOT intended to be a universal consent.
- Proposition #2-The MC is NOT intended to replace existing informed consents for treatment.
- Proposition #3-The MC is NOT intended to replace HIPAA authorizations or consents/authorizations for use and disclosure of highly sensitive health information required by state law. But, the MC must NOT be inconsistent with those forms
- Proposition # 4-The MC is a focused consent for the specific purpose of authorizing disclosure of health information to the HIE and the subsequent use by HIE participants.

Annulis directed the group to consider #4 as a critical issue, to determine the focused intent of this particular form. Annulis asked if there is a legal objective or requirement for consent, and if there are consumer issues/objectives the group would want to address by virtue of the form (i.e., treatment-related disclosure for HIPAA purposes that doesn't require consent from the patient—providers can share information without it, and can share information between the primary care provider and specialist(s) for treating a patient for a specific condition). The HIE is intended for anticipatory treatment; Annulis also asked if the group felt this fell under "treatment" as defined under the privacy rule, or if there was a legal obligation to get consent for this endeavor.

A participant reiterated one of the stated intents, to keep focus on patient, and noted some concerns they may have (dislike of multiple forms, concern about where records are, sharing information). Annulis wondered if commitment to the patient was a legal requirement or patient relations requirement. Some discussion followed about ethical requirements for physicians, and that anticipatory depositing of information requires consent under current law. Johnson said the system as envisioned is structured so that medical records themselves (except public health-related) would stay with the provider, while locator information uploaded to the state-level exchange would point to where records were located, and information would thus be sent directly from provider A to provider B. This model is a strongly supported process by stakeholder groups.

Additional discussion followed about practical use matters (i.e, who can access and under what circumstances, who will get notification that information was accessed, how does any design change affect what will be used). One participant expressed concern about what particular fields will go to the data warehouse, such as mental health records, HIV information, or alcohol and substance abuse. Others added that consent would not supercede extant laws, and that the HIE would still have to work within the constraints of current laws. Johnson said some states are looking at different types of options for mental health, etc. Martin noted that the legal WG will not have final word on who the final users of HIE will be, and so must remain reactive to the overall path of the project, while providing input on who's going to be authorized and how a health care provider defined (i.e., providers of alternative medical services, etc.).

Other discussion arose about health care clearinghouses and state agencies, and whether these entities would use identifiable or de-identified data. IPAA: One group member thought issues with public health disclosure, compliance with HIPAA and state disclosures would be a potential quandary. Johnson noted that specific guidelines about de-identified data are outlined in SB 547; another member added that he thought data should be reserved for licensed providers only. He and others expressed concerns about health plans gathering data. Thomas pointed to HB 1254 for its information about data use for surveillance purposes; she added that the legislation will be helpful to shape where the group is going. Johnson added some comments from the Privacy and Security workgroup meeting held Sept. 21, which included a lively discussion of what kind of data would be accessible. Other concerns, including linkage with third party payers and user-defined personal health records, and special consent for researchers were judged to be latter parts of the HIE discussion, as its primary focus is on facilitating the treatment process among providers only.

A participant noted that with no control over users and how the HIE would be set up, the consent form may take a larger appearance. Different accommodations, such as check-off categories, were discussed. Others questioned the process of handling more paper in busy provider offices. Martin cited reasons why a streamlined and focused form narrowly targeted to treatment providers might have pros and cons; another participant noted that people are used to checking off a box that gives consent for or against their information going to others. Profiling patients via third party payers was the group's most serious concern. Johnson noted, however, that the information contained in the HIE would be whatever information the HIE feels necessary to have in order to identify a patient, which would not comprise clinical data. Johnson continued that the electronic records task force wanted to cut out the process of having providers needing to contact each other, and that an agreement to be part of the HIE means agreeing to allow information to be accessed by the HIE and/or other providers, it doesn't store clinical data nor does it automatically give out information. The HIE would require a provider to take an additional step to release records, and Johnson added that even with streamlined procedures it would take time to move electronic records between providers, perhaps more time than copying. Some practical matters regarding implementation were discussed, such as the lack of electronic data in many provider offices and authentication procedures. Participants expressed concern that the technology might be insufficient to glean out the most pertinent information necessary in a record, and that there were too many steps in the process, especially in times of critical need (i.e., emergency rooms). Johnson redirected the group back to the issue of developing a mechanism to start the process. Thomas added that HB 1254 proposes an advisory body to oversee access and other areas of concern.

Amid further discussion of system architecture and information access concerns, Thomas said the group's refined goal was to focus on consent for treatment access, while recognizing and highlighting concerns with other uses; these areas need to be fleshed out and developed by other bodies. A participant noted that while keeping the group's work simple was easy, operationalizing could be a nightmare. Annulis noted that providers don't generally "need" legal consent to share information, but from a patient relations perspective, the group might want to consider having one. Various aspects of consent were discussed, including: issuing a model acknowledgement paragraph to be included in HIPAA; work on disclaimers in case a breach occurs; and allowing access from outside the system. Other resources were also suggested, such as the communication plan from the HIPAA group for consumers; and a consent form from Ohio with proposed provisions including basic contact information and medical care, with separate parts for providers, plans, and treatment. For anything other than treatment, the form allows check-offs to disallow certain records and specific restrictions.

Martin noted the direction of the group's discussion; one route is to rely on HIPAA, while another also included a form needed to protect people with highly sensitive information. Some discussion arose as to whether HIE was considered a business associate of HIPAA, as well as the time frame for consent and how patients would be notified that their records had been accessed. The group also noted that if information were sent via phone, e-mail or fax, the conduit of consent is the same, and wondered if the HIE were to act as a mere conduit, or something else. One participant thought that phone calls or faxes still require a judgment call, while electronic exchange removes this. Martin noted that the group now had two levels to consider—the release of information regarding services provided to a patient residing in a HIE, and the extra step of judgment missing when the HIE pulls records and transmits them without a judgment call. Other concerns arose among group members surrounding: possible duplication of records, getting the correct notification forms to patients, and the ability for patients to opt out of sharing their information.

Martin noted some legal concerns such as the lack of clarity that the HIE would be considered already protected, and whether not having a separate consent form would open it up a potential backlash. Martin suggested the group choose one of two options: develop a form to go to areas pre-empted by HIPAA, or take a stab at a more universal form only for treatment by authorized users. Johnson added that the multi-state collaborative was focusing on coming up with a matrix of things states would have to provide each other in the format of use cases. Thomas noted the lack of time to continue discussion, and asked group members to gather their thoughts on narrowing the HIE user and purpose. Written comments were to be sent to Kathy Karsten by Tuesday, Oct. 12 to compile for the next meeting. Thomas agreed to work on fleshing out the issue and try to focus the group's mission and project scope.

The meeting was adjourned at 12PM.