



Legal Work Group

Developing a Uniform EHR/HIE
Patient Consent Form



HISPC

- Health Information Security and Privacy Collaboration (HISPC) is a federal initiative to study privacy and security issues related to health information exchange (HIE)
- HISPC's phase 1 goals were to:
 - identify both best practices and challenges
 - develop consensus-based solutions that protect the privacy and security of health information, and
 - develop implementation plans to implement solutions.
- 33 states and 1 territory participated in the collaboration



HISPC-Illinois

Implementation Recommendations

1. Develop systematic, comprehensive approach to promoting HIE
2. Adopt universal standard for patient identification
3. Develop standards for consistent and available privacy and security expertise for organizations.
4. Establishment of core competencies for staff education and training in electronic health information, privacy and security.
5. Develop educational materials for consumers
6. Extend and promote, national Stark, e-prescribing and anti-kickback relief regulations.
7. Provide recommendations for use of multidisciplinary teams in the acquisition of new IT solutions.
8. Include in lead state agency/organization legal staff with expertise in privacy and security to guide integrated state efforts.



HISPC Phase II

The purpose of phase 2 is to implement proposals produced during the initial phase of the project.



HISPC-Illinois II

Project Proposal

- The priority for Illinois as HISPC enters phase 2 is to move the public-private partnership outlined in the Electronic Health Records (EHR) Taskforce report and supported in the HISPC-Illinois State Implementation Plan forward in the areas of privacy and security. “Solution 8,” of the “State Implementation Plan – Illinois” provides for the “lead state agency/organization” to have expertise in privacy and security to guide state activities.
- Consistent with the spirit of that implementation solution, HISPC-Illinois II will set up an expert work group to prepare draft privacy and security policies and recommendations for consideration by the governance structure of a state-level health information exchange (HIE). Another work group will prepare a uniform patient EHR/HIE consent form for possible use by the state-level HIE, clinicians, health care facilities and other providers.



HISPC-Illinois II Structure

Steering Committee

Privacy and Security
Work Group

Legal
Work Group



Legal Work Group

Develop a model uniform patient EHR/HIE consent form for possible use by ILHIN, clinicians, health care facilities and other providers. The Legal Work Group is also tasked with the development of a plan to disseminate the consent form and encourage its use.

- Outline issues to be addressed in the model consent form.
- Preparing a draft form for review by stakeholders.
- Adopt a “Model Uniform Patient EHR/HIE Consent Form.”
- Preparing a plan for the dissemination of the model consent form and to encourage its use by stakeholders.



Work Plan

- **First Meeting** – September 26
 - Discuss approaches to achieve the work group task.
 - Discuss and adopt an outline of the issues to be addressed in the “Model Uniform Patient EHR/HIE Consent Form.”
 - Discuss work assignments for next meeting.

- **Second Meeting** – Tentatively scheduled for October 10
 - Discuss and approve a draft “Model Uniform Patient EHR/HIE Consent Form” for review by stakeholders.



Work Plan Continued

- **Third Meeting** – Tentatively scheduled for November 14
 - Finalize the “Model Uniform Patient EHR/HIE Consent Form” based upon stakeholder feedback.

- **Fourth and Final Meeting** – Tentatively scheduled for December 5
 - Review and adopt a plan that will address the dissemination of the “Model Uniform Patient EHR/HIE Consent Form” to health care providers and to encourage its use by those providers.



How We'll Communicate with Our Stakeholders

- Via E-mail
- Via HISPC-Illinois II Web site – www.idph.state.il.us/hispc2
- Via HISPC-Illinois II Listserv



HIE Model Consent

- Purpose
- Content
- Considerations



Purpose

- 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.



Content: Authorized Users

- Who will be authorized to access information contained in the HIE?
 - “Health care providers” only?
 - How should “health care provider be defined (e.g., licensed entities and professionals only)?
 - Health plans & payors?
 - Health care clearinghouses (as defined in HIPAA)?
 - State agencies for public health or other purposes?
 - Others (e.g., PBMs, researchers, other insurers)?



Content: Information to be Disclosed

- What is the scope of the information to be disclosed to the HIE?
 - Medical information only?
 - Should definition differ from PHI under HIPAA?
 - Financial/payor information?
 - Other?
- Should the MC adopt an “all or nothing approach” or allow a patient to disclose only selected information under a “check the box” approach?
 - Should there be any consequences or disclaimers attached to limitations?



Content: Authorized Uses

- What uses should be authorized by the MC?
 - Should authorized uses be limited to treatment or, alternatively, to treatment, payment and health care operations (as defined under HIPAA)?
 - If the authorized uses are limited to TPO (and authorized users are limited to providers, health plans and health care clearinghouses), is any consent required for the disclosure of PHI to the HIE in anticipation of use for TPO?
 - Should any use beyond TPO be authorized (e.g., research, outcomes measurement)?
 - Might the state want to access the HIE for various public health or other purposes?
 - Should the form embody a "check the box" approach that allows the individual patient to authorize (or not) specific uses?



Content: Additional Provisions

- Revocation right and consequence?
- Expiration date or event?
- Patient Rights?
 - Is an individual entitled to an accounting of disclosures?
 - Should individuals be entitled to access and/or edit their data in the HIE?
- Who can sign?
 - “Personal representative”?
 - Can a minor revoke a parent’s or guardian’s prior consent?
- How should the contractors of HIE participants be handled?
- Acknowledgement of potential re-disclosure?



Other Considerations

- Impact of health information confidentiality laws
 - HIPAA—Is the disclosure of health information to the HIE a disclosure for TPO?
 - Impact of other federal laws (e.g., FSAR)
 - State law considerations
 - How does Illinois law affect the content of the MC (e.g., AIDS Confidentiality Act? Genetic Information Privacy Act? Medical Patient rights Act)?
 - Does the MC need to embody a HIPAA preemption analysis?
- Opt-in or opt-out process?
- Existing Templates
 - HIPAA authorizations
 - Forms developed by other states