

Testimony
Illinois Health Information Exchange
Data Security and Privacy Committee
Tuesday, July 17, 2012
Via teleconference

Good afternoon, Mr. Chairman and members of the committee. I am Michael Berry, Project Manager for HLN Consulting, LLC, a health information technology company based in San Diego. I have been with for HLN for over ten years, building immunization registries to connect providers to public health, connecting public health to health information exchange, and assisting HIEs with privacy and consent policy and technology. I have contributed to the Health Information Security and Privacy Collaborative and other ONC efforts related to privacy and security. And I am currently engaged with OHIT, in collaboration with the SHARPS project at the University of Illinois – to define a technical architecture and develop a prototype for a privacy and consent layer within the Illinois HIE.

I would like to thank you for the opportunity to provide testimony today regarding the operational aspects of obtaining and managing consent in an HIE; specifically, regarding different strategies being used in HIEs around the country.

First let me make the distinction between 'push' messaging, such as the Direct messaging in ILHIE Phase 1, and 'pull' messaging, such as the aggregated query-response in ILHIE Phase 2. The consent strategies I'm discussing today are generally limited to the 'pull' model – many HIEs offer both a push service such as results delivery, and a pull service for on-demand query-response; and it's typical for the results delivery component to have no consent function, and the query service to have one.

As you know, broadly speaking there are a number of high-level consent models that an HIE may choose to implement. These range from no consent, to opt-out, opt-out with exceptions, to opt-in, and opt-in with restrictions; or a combination of these models. The selection of a consent model is typically influenced by federal and state law, HIE policy, as well as the input of stakeholders – providers, patients, public health, and others.

That consent model decision impacts the operational requirements for obtaining and managing consent. For example, the expected volume of consent requests in an opt-out HIE may be lower than that of an opt-in HIE. An opt-in system is more likely to benefit from a consent collection mechanism that works in real-time and is integrated into the patient encounter; as opposed to an asynchronous, offline process developed for an opt-out system. A partial or hybrid consent model will require more information in the opt-in or opt-out transaction, potentially requiring additional patient education efforts and more complex systems to manage the consent data that is collected.

HIEs today collect consent preferences from patients using a number of methods which can be categorized into two groups: directly from the patient to HIE, and indirectly through the patient's provider.

- ⤴ The primary advantages of the indirect method, through the patient's provider, are that the HIE can rely on the provider to identify and authenticate the patient, and that the consent action can be integrated into the patient encounter.
- ⤴ The primary advantages of the direct method are less burden on the providers – who are not always able to absorb the added time and cost of collecting consent – and potentially more control in the hands of patients.

In both methods, the consent is collected from the patient (or the patient's authorized agent) either electronically (such as on a web-based form), on paper, or orally (which may be in person, or over the telephone).

When the HIE is collecting the consent directly, a key challenge is to identify the patient and to authenticate the consent – to be sure that the consent is coming from the patient or from someone authorized to provide consent on behalf of the patient. This can be difficult. The same name-matching challenges that HIEs encounter when exchanging data with providers are present in accepting consent directly from patients. Regarding authentication, the required level of assurance is a policy question for the HIE, and it may be influenced by the consent model that has been chosen. We have encountered examples in other states ranging from an opt-out web form that only requires basic demographic information (name, address, DOB, phone); to a paper opt-out form that requires the demographic information plus a signature by a state-licensed health care provider or a notary public stamp; to a web-based opt-in form that requires demographic information plus a component of the patient's Social Security number. We are also aware of commercial vendors that market patient identity proofing services to HIEs, where the web form is supplemented by a series of questions derived from the patient's credit report. Another option is to require a token – such as a PIN number – obtained from patient's provider. Clearly, there is a trade-off between the level of assurance and the patient's convenience.

When the provider is collecting consent, there are a few key decision points: First, the consent can be a provider-by-provider consent or a global HIE (multi-provider) consent. Second, the consent can be stored by the provider only, or sent to the HIE; generally, a multi-provider consent requires that the consent be transmitted to the HIE. And third, the consent can be solely an assertion by the provider – the provider asserts that the patient consented – or it can contain some token from the patient such as a signature on paper or an electronic signature captured in the provider office.

It's also worth noting that in the opt-out model, some HIEs – in order to better ensure informed consent – adopt an “opt-out with notice” policy, where all patients receive notice (either through the provider or directly from the HIE) of their record going in to the HIE and of the opt-out policies and procedures that will apply.

Once the consent has been collected and stored – either at the provider's office or at the HIE – the HIE needs to provide a way for the patient to change it. In the opt-out model with an opt-out form, typically there is a companion opt-out reversal form. In the opt-in model with an opt-in form, typically a patient can simply submit a new form to update the existing preferences. To move beyond that level of complexity – to allow a patient to view his or her current consent preferences, and update them – generally requires a web-based patient portal, with the higher level of patient identity assurance and authentication requirements that go along with that. Many commercial HIE vendors offer patient portal products, though the implementation of these products in state HIEs is still in its early phases.

What about granular preferences? I mentioned earlier that a partial or hybrid consent model will require more information in the opt-in or opt-out transaction and make it more complex. It's important to note that many state HIEs have incremental deployment strategies that include a less ambitious initial phase – such as an all-or-nothing consent approach, a static set of information sources and purpose of use, an unlimited duration of consent – followed by more ambitious future phases. So as we look around the country we do not currently see a lot of granular preferences being offered to patients in their opt-in or opt-out forms, but that doesn't necessarily reflect the changes under development as HIEs strive to ensure meaningful choice for patients. In one state we are aware of, the opt-in form allows patients to select individual provider organizations who will be allowed to access the patient's record, or to limit the purpose of use to emergencies. In a pilot project in another state, the opt-in form was required to be signed at each provider organization, and it authorized data only from that organization into the HIE.

In conclusion, the operational requirements of obtaining and managing consent in an HIE are influenced by the consent model selected by the HIE; and once the consent model has been chosen there are important tradeoffs to consider in terms of collecting the consent, storing and transmitting the consent, and updating the consent.

Mr. Chairman and members of the committee, thank you for giving me the opportunity to speak to you today.

Acknowledgments:

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