Opt-in Versus Opt-out: Consent Models for Health Information Exchange through Missouri's Statewide Health Information Exchange Network

As part of its development of a larger privacy and security framework, MO-HITECH's Legal/Policy Workgroup (the "Workgroup") is considering to what extent, and how consumers should have control over the exchange of their personal health information through Missouri's statewide HIE network. The purpose of this document is to provide an overview of the two main models for consumer consent to exchange personal health information through the exchange, often referred to as "opt-in" and "opt-out".

- Opt-in: Typically requires affirmative authorization from the consumer, often through signing a standardized consent form, before a consumer's health information may be exchanged through the network.
- Opt-out: Typically requires that the consumer is given notice – through mailings, brochures, posted notices or other means - and allows a consumer's health information to be exchanged through the network unless and until the consumer formally requests that it not be.[1]

The choice between opt-in and opt-out is one of multiple decisions when constructing a consumer consent policy for statewide health information exchange. Other features and policy questions may include:

- the nature and breadth of consumer outreach and education efforts related to the consent decision;
- the durability and revocability of consumer consent;
- the ability to "break the glass" to obtain health information in emergency situations when a consumer has not had the opportunity to grant or deny consent;
- whether and to what extent consumers may control what providers are allowed to share and/or access their information;
- whether and to what extent consumers may exclude certain types of health information;
- whether the exchange should limit, exclude or otherwise afford special treatment for categories of specially protected health information, such as HIV, mental health and abortion services; and
- the extent of security, enforcement, and remedies in place.

The purpose or use of exchanging personal health information is another factor influencing consent policies. Consumers often have different levels of comfort with information exchanged among providers for the purpose of treatment, than when other parties and uses are contemplated. In developing its recommended privacy policies, the Workgroup has operated under the assumption that the statewide exchange of personal health information will be between providers and only for purposes of treatment, and that policies and protections will be in place to ensure that only authorized providers who have a treatment relationship with the consumer will be able to access to information within the exchange.

Another key consideration in developing consent policies is the desire to create consistency with other exchange efforts across state lines. This is particularly important in Missouri, where major regional healthcare markets cross state lines. Some have called for a single set of national standards related to consent policies. While various national and federal efforts are exploring legal and policy issues associated with HIE, including the Health Information Security and Privacy Collaborative, variation in state law requirements has, to date, prevented a single national solution. The Workgroup continues to monitor these efforts, but must move forward to develop an approach and consent framework in the context of Missouri State law. An important part of this work requires understanding the policies of existing Missouri HIE efforts and its eight border states; please see Appendix A for an overview of what is known about HIE and border states' consent policies.

[1] An opt-out model is not the same as a "no consent" model. Under a "no consent" model, consumers' health information is automatically included in an exchange. They cannot opt-out. The Indiana Health Information Exchange (IHIE) serves as an example. It does not require express patient consent for participation in the exchange. It also does not include certain sensitive health information that requires patient consent for disclosure by law (e.g. information from federally-assisted substance abuse treatment programs covered by the federal Confidentiality of Alcohol and Drug Abuse Patient Records regulations at 42 CFR Part 2).

Considerations Related to an Opt-in Versus Opt-out Consent Model

The choice between opt-in and opt-out is informed by multiple considerations, outlined in greater detail in the chart below. In Missouri, the greatest differentiator among these considerations is state law. While it is unclear whether authorization is required to share personal health information under state law in Missouri, authorization is clearly required for certain types of specially protected of health information. Thus, Missouri state law requires either that a consumer opt-in, or that certain specially protected health information be screened out.

Considerations	Opt-in Implications	Opt-Out Implications
Consumer Trust Statewide HIE represents a paradigm shift in the way health information is shared: from a "one-to-one" exchange in which consumers connect points of care, to a "many-to-many" in which information may be exchanged without consumers' active engagement. To engender public support for this effort and to ensure individual consumers' interests are protected, consumer trust is paramount.	▪ Depends on deployment approach. ▪ Some argue act of consumer signing consent increases likelihood that consent is meaningful and knowing.	▪ Depends on deployment approach.
State and Federal Legal Requirements Federal law under HIPAA does not require patient consent to exchange personal health information for the purpose of treatment, payment or healthcare operations.[2] Case law in Missouri is ambiguous as to whether consent is required for the release of personal health information generally. However, State statute requires authorization to exchange certain types of sensitive health information, including genetic information, abortion services, mental health and some substance abuse treatment services. It is unclear whether authorization is required for the exchange of HIV tests and services.	▪ Provides maximum legal protection by providing a record of patient permission to exchange personal health information. ▪ Required to share sensitive health information in Missouri.	▪ Does not meet state legal requirements for sharing information related to genetic information, abortion, mental health and substance abuse services. ▪ Unclear whether it meets state legal requirements for exchange of HIV information.
Clinical Value of the Information To have value, the statewide health information exchange must include information necessary to provide effective treatment. Without robust medical data, doctors will not participate and the exchange will not be sustainable.	▪ Allows maximum information sharing under current state law.	▪ Requires exclusion of some types of sensitive health information under current state law. ▪ May result in a "thin" system limited to data automatically eligible for exchange (e.g. lab results, summary record information)
Technical Feasibility and Cost While technology solutions exist to accommodate a wide range of consent models and features, in general, the cost and technical complexity increase with requirements to exclude certain types of data and/or providers, particularly if the policy calls for such sorting at the consumer level.	▪ Technology models exist for both options.	▪ Technology models exist for both options; the need to exclude certain types of sensitive health information could increase costs.
Administrative Burden and Implementation Cost The deployment of consent features require varying degrees of involvement, burden and cost from providers and other HIE participants.	▪ Requires educational strategies by HIO and providers ▪ Likely to be bundled with notice and consent processes currently used for health information[3]	▪ Eliminates need to gather patient consent ▪ Efforts required to ensure consumers are aware of exchange and have opportunity to opt-out[4] ▪ Providers may still want documentation

[2] HIEs wishing to include information from federally-assisted alcohol and substance abuse centers, for instance, must obtain patient consent to exchange such information or risk being found in violation of federal law. *See* 42 CFR Part 2.

[3] Micky Tripathi, David Delano, Barbara Lund and Lynda Rudolph. "Engaging Patients for Health Information Exchange." Health Affairs. Volume 28, Number 2. March/April 2009.

[4] CareSpark, an HIE that spans areas of both Tennessee and Virginia serves as a case in point. Because state laws in Tennessee and Virginia do not require express consent from patients to share general clinical information electronically for treatment purposes or for other purposes expressly permitted under law, CareSpark relies on an opt-out model. However, CareSpark requires that health care providers educate consumers about CareSpark and how consumers' information is exchanged through the HIE. To facilitate providers' education of consumers, CareSpark trains provider organizations on the opt-out process and supplies them with written educational materials. Other HIEs that rely on opt-out models (e.g. the Nebraska Health Information Initiative and Maine's HealthInfoNet) also allow consumers to opt-out online, and provide significant amounts of educational content on their websites.

Conclusion

Evidence shows that both opt-in and opt-out consent models can generate sufficient patient and provider participation to achieve the critical mass necessary for system function and the realization of key goals. Opt-out models typically show slightly higher overall consumer participation rates; while opt-in models require more effort to ensure consumer participation and, if not done correctly, could result in fewer consumers participating in the exchange.[5] The main advantage of an opt-in model, on the other hand, is that it permits the inclusion of specially protected personal health information. States pursing an opt-out consent model, such as Nebraska, typically have elected to exclude specially protected information. Some states, such as Kansas, are seeking statutory changes that would eliminate or limit state statutory requirements so that they would not apply to specially protected information in the exchange. Still others, like Tennessee, do not have state law requirements limiting the exchange of sensitive health information.

Both patient and provider participation are necessary to facilitate better care delivery and advance other societal goals (e.g., improved public health), as well as to ensure the viability of HIE. Adoption of an appropriate consent model, coupled with responsible policies dictating the types of information included in the exchange, the nature and number of entities granted access to the information, the purposes for which the information can be used, the durability and revocability of consumer consent, and the extent of security, enforcement, and remedies in place, will help to build trust in Missouri's statewide HIE network while meeting clinical goals.

[5] Melissa Goldstein and Alison Rein. "Consumer Consent Options for Electronic Heatlh Information Exchange: Policy Considerations and Analysis." Prepared for the Office of the National Coordinator for Health IT. March 23, 2010.

Appendix A

Regional HIO	Consent Policies	Language/Addl Information
Kansas City Bi-State HIE (KC-BHIE)	Under development	➢ Privacy, Security, and Legal Committee is developing policy recommendation ➢ Kansas and Missouri are currently considering different consent policies
Lewis and Clark Information Exchange (LACIE)	Opt-out	
Springfield	Under development	➢ Monitoring MO-HITECH guidance
St. Louis Integrated Health Network	Under development	➢ Beginning to develop consent language ➢ Monitoring MO-HITECH guidance
CareEntrust *(Personally controlled record)*	N/A Consent policies refer to the consumers' desire to participate in a PHR	➢ Consumers are given access to the CareEntrust PHR through medical benefit enrollment ➢ Consumers control provider access to the information in their PHR at the organizational level

Table 1. Missouri HIE Effort Consent Policies

State	Consent Policies	Sensitive Health Information	Lead Organization & Recommendations
Arkansas	Under development	Not yet addressed	**Arkansas Health Information Exchange -** http://recovery.arkansas.gov/hie/ Legal & Policy Workgroup began meeting in March 2010.
Illinois	Under development	Not yet addressed	**Illinois Health Information Exchange -** http://www.hie.illinois.gov/ The Privacy & Security Working Group will recommend how to address the issue of patient control of data and patient consent in the design of the state-level HIE.
Iowa	Under development *Opt-out*	Seeking changes under state law	**Iowa eHealth –** http://www.idph.state.ia.us/ehealth/default.asp *Workgroup Recommendation* – Establish clear patient consent policies within the HIE privacy and security framework**;** Consider statutory changes in Iowa law to allow protected health information to be exchanged among providers for treatment-related purposes without additional patient consent
Kansas	Under development *Opt-out*	Seeking changes under state law	**Kansas e-Health Advisory Council –** http://www.kanhit.org/ It is anticipated that the Council will seek legislative changes in support of an opt-out model.
Kentucky	Opt-out	Unclear whether included	**Kentucky Health Information Exchange-** http://chfs.ky.gov/os/goehi/khie.htm Patients have the right to opt-out at any time and not participate in the exchange of their personal health information through the KHIE. There is no emergency access if a patient has chosen to opt-out.
Nebraska	Opt-out	Specified classes of sensitive data are excluded from exchange	**Nebraska Health Information Initiative -** http://nehii.org/ Participation in the Nebraska Health Information Initiative (NeHII) is voluntary. However, health information will be included in NeHII unless the consumer opts out. Some types of specially protected health information is excluded from the exchange.
Oklahoma	*Voluntary* Opt-in	Under consideration	**Oklahoma Health Information Exchange** -http://www.okhca.org/ State Legislature ordered the creation of a standard authorization form for health information exchange. Providers who use the *optional* form and follow are immunized from liability under state privacy laws. (Oklahoma SB 1420)
Tennessee	Opt-out	Not yet addressed	**Health Information Partnership for Tennessee -** http://www.hiptn.org/ The Privacy and Security Workgroup will revisit its opt-out/patient notification recommendations upon review of sensitive health information.

Table 2. Border State Consent Policies