



Illinois Office of Health Information Technology



Patient Consent Models

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Issues

- ▶ 1. **Patient Choice**: Should patients be given a choice with regard to health care providers and others using an HIE to exchange a patient's health care data?
- ▶ 2. **Opt-in v. Opt-out**: If patients are given a choice, should all patients be provided the option to affirmatively consent to HIE inclusion ("opt-in") or should they be included unless they affirmatively decline inclusion ("opt-out")?

Issues cont'd

- ▶ 3. **Granular Sequestration**: Should patients have the ability to sequester specific elements of their patient record from specific providers (“granularity”) or should the entire patient record be excluded from the HIE if a patient desires some data sequestered (“all in or all out”)?
- ▶ 4. **Data Hidden v. Excluded**: If a patient chooses against use of the HIE, may the data still be collected by/made accessible to the HIE for mandatory public health reporting or for emergency medical treatment?

Current Federal Law – HIPAA

- ▶ Federal HIPAA Privacy Rule: patient consent required for all PHI disclosures unless expressly permitted.
- ▶ Exception: exists for certain disclosures for purposes of “Treatment, Payment and Healthcare Operations” (T-P-O), for public health activities, for research purposes and for other legally required disclosures.
- ▶ HIPAA, 45 CFR§164.506
- ▶ HIPAA, 45 CFR§164.512(b)
- ▶ HIPAA, 45 CFR§164.512(i)

Federal Guidance

- ▶ U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR): patient data can be transmitted through an HIE for treatment purposes without the need of a prior patient consent.
- ▶ HHS Centers for Medicare & Medicaid Services (CMS) in 2011 issued rules regarding Accountable Care Organizations (ACO): encourage the sharing of patient data among participants using a patient “opt-out” system, even for T-P-O purposes.
- ▶ HHS Office of National Coordinator for Health Information Technology (ONC) recently issued guidance that patients should be provided a “meaningful choice”, either on an “opt-in” or “opt-out” basis, even for T-P-O purposes,

Five Core Consent Models

- ▶ 1. **No-consent**: Health data is automatically eligible for exchange by the HIE without requiring patient consent. (No requirement beyond HIPAA regulations).
- ▶ 2. **Opt-out**: Health data is automatically eligible for inclusion in the HIE, but each patient must be given the opportunity to opt-out in full.
- ▶ 3. **Opt-out with exceptions**: Health data is automatically included in the HIE unless patients opt out. Patients can also choose to limit the extent of inclusion. They can exclude specific data, limit the flow of data to specific providers or organizations, or allow the exchange only for specific purposes.

Five Core Consent Models cont'd

- ▶ 4. **Opt-in**: Patient consent is required to have health data included in/transmitted through the HIE.
- ▶ 5. **Opt-in with restrictions**: Patient consent is required to have health data included in the HIE. Patients may also choose which data is included, which providers or organization can receive the data and the specific purposes for the exchange.

National Adoption

Opt-out:	27 States
Opt-In:	12 States
No Consent:	3 States
TBD:	8 States