

## ILHIE Authority Data Security and Privacy Committee

### Briefing Summary: Policies # 1, 3 (Panel #1) -- Patient Choice, Opt-in/Opt-out

1. Patient Choice. Should patients be granted a choice with regard to the use of a health information exchange (HIE) by clinical treatment professionals and others for the exchange of a patient's health care data?

3. Opt-in v. Opt-out. If patients are provided a choice with regard to the use of HIE for the exchange of patient data, should all patients be provided an option to affirmatively decline from HIE inclusion (an "opt-out") or the option of affirmative consent for HIE inclusion (an "opt-in")?

### Federal Guidance

- The Federal HIPAA Privacy Rule currently requires patient authorization/consent for all PHI disclosures unless expressly permitted. A specific exception exists for certain disclosures for purposes of "Treatment, Payment and Healthcare Operations" (T-P-O)<sup>1</sup>, for public health activities,<sup>2</sup> for research purposes<sup>3</sup> and for other legally required disclosures. A provider's solicitation of a patient consent for disclosure for T-P-O purposes is optional.
- U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) has been of the view that patient data can be transmitted through an HIE for treatment purposes without the need of a prior patient consent.<sup>4</sup> The granting to patients by providers and/or the HIE of a right to "opt-out" or "opt-in" to the use of HIE is optional.
- HHS Centers for Medicare & Medicaid Services (CMS) in 2011 issued rules regarding Accountable Care Organizations (ACO) which encourage the sharing of patient data among participants using a patient "opt-out" system, even for T-P-O purposes.<sup>5</sup> (Such T-P-O data exchange restrictions go beyond current HIPAA.)
- HHS Office of National Coordinator for Health Information Technology (ONC) recently issued guidance to the recipients of HIE planning grants<sup>6</sup> that patients should be provided a "meaningful choice", either on an "opt-in" or "opt-out" basis, even for T-P-O purposes, for participation in a robust bilateral HIE which aggregates clinical data. (Such T-P-O data exchange restrictions go beyond current HIPAA.) No "meaningful choice" is required for simple point-to-point unilateral directed exchange (e.g. NwHIN Direct).

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<sup>1</sup> HIPAA, 45 CFR§164.506

<sup>2</sup> HIPAA, 45 CFR§164.512(b)

<sup>3</sup> HIPAA, 45 CFR§164.512(i)

<sup>4</sup> OCR, "Collection, Use, And Disclosure Limitation", a "companion document" to the 2008 ONC Framework, p. 4, FAQ #1, "Individual Choice", p. 4, FAQ #2.

<sup>5</sup> MSSP Final Rule, 79 Fed. Reg. 67803 (Nov. 2, 2011).

<sup>6</sup> Program Information Notice—003, "Privacy and Security Framework Requirements and Guidance for the State Health Information Exchange Cooperative Agreement Program," March 23, 2012.

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- HHS ONC issued on May 15, 2012 a Request for Information regarding the Governance of the national HIE (NwHIN)<sup>7</sup> which suggests that patients should be provided a “meaningful choice”, either on an “opt-in” or “opt-out” basis, but admits the prospect of making an exception to patient choice for data exchange using simple point-to-point unilateral directed exchange (e.g. NwHIN Direct), or for purposes of “treatment”. (Such T-P-O, or possibly just P-O, data exchange restrictions go beyond current HIPAA.)

### Illinois Status Quo: No Patient Consent for T-P-O, Mixed Opt-in/Opt-out for General & Special PHI

- General PHI: no patient authorization/consent required
  - Disclosure for “Treatment, Payment and Healthcare Operations”: no patient authorization required<sup>8</sup>
  - Disclosure in emergency: no patient authorization required<sup>9</sup>
  - Disclosure required by law/ for public health reporting: no patient authorization required<sup>10</sup>
  - Disclosure for Research (data analysis): no patient authorization required<sup>11</sup>
- General PHI: opt-out
  - Disclosure for use in facility directories: opt-out<sup>12</sup>
  - Disclosure to patient’s family/caregivers: opt-out<sup>13</sup>
- General PHI: opt-in
  - Disclosure for “Marketing” uses: opt-in<sup>14</sup>
  - Consent for Experimental Research Trials: Fed – FDA: Protection of Human Subjects<sup>15</sup>; IL - prior informed consent for participation in “research program or an experimental procedure”<sup>16</sup>; “experimental research or medical procedure”<sup>17</sup>
- Special PHI: opt-out
  - HIV/AIDs consent for testing: opt-out, except if for treatment or data is de-identified<sup>18</sup>

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<sup>7</sup> “Nationwide Health Information Network: Conditions for Trusted Exchange”, 77 Fed. Reg. no. 94, at 28543.

<sup>8</sup> HIPAA, 45 CFR §164.502, §164.506; 410 ILCS 50/3(d)

<sup>9</sup> HIPAA, 45 CFR §164.512(j)

<sup>10</sup> HIPAA, 45 CFR §164.512(a),(b)

<sup>11</sup> HIPAA, 45 CFR §164.512(i)

<sup>12</sup> HIPAA, 45 CFR §164.510(a)

<sup>13</sup> HIPAA, 45 CFR §164.510(b)

<sup>14</sup> HIPAA, 45 CFR §164.508(a)(3), §164.501

<sup>15</sup> 21 CFR 50

<sup>16</sup> 410 ILCS 50/3.1

<sup>17</sup> 20 ILCS 301/30-5

<sup>18</sup> 410 ILCS 305/4

## ILHIE Authority Data Security and Privacy Committee

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- Immunization registry consent for inclusion: opt-out<sup>19</sup>
- Special PHI: opt-in
  - Mental health/behavioral health/developmental disability: opt-in, except therapist disclosures to staff<sup>20</sup>
  - Psychotherapy notes: opt-in<sup>21</sup>
  - Substance abuse: opt-in<sup>22</sup>
  - Genetic test data: opt-in, except if data is de-identified, or for program evaluation<sup>23</sup>
  - HIV/AIDs - consent for testing for insurance: opt-in<sup>24</sup>
  - HIV/AIDs – consent for disclosure of test results: opt-in, except if data is de-identified, or for program evaluation, or for public health<sup>25</sup>

#### *Policy Option: Keep Status Quo*

##### **Pros**

- Minimizes disruption to current provider workflow/practices and administrative overhead (less likely an issue at large hospitals, more likely at small provider practice level)
- Maximizes flow of data to HIE for T-P-O; enhances utility of HIE to providers and patients; data for research and quality reporting not skewed by selective omission of data
- No distinction required between HIE models (simple point-to-point unilateral directed exchange (e.g. NwHIN Direct) and robust bi-lateral HIE which aggregates clinical data).

##### **Cons**

- Barriers to HIE due to ambiguities in current IL statutes still not addressed
- Some specially-protected PHI still requires opt-in or opt-out to be disclosed
- HIE's secondary uses of data may still require patient authorization
- Patients desiring to sequester their general PHI from inclusion in HIE not accommodated; between 0% to 3% of patients (estimate)

#### *Policy Option: Patients Permitted to Opt Out of PHI delivery through HIE*

##### **Pros**

- Patient given option to protect any information which patient considers highly confidential

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<sup>19</sup> 410 ILCS 527/15(a)

<sup>20</sup> 740 ILCS 110/3, 5, 9

<sup>21</sup> HIPAA, 45 CFR §164.508(a)(2)

<sup>22</sup> 42 CFR Part 2

<sup>23</sup> 410 ILCS 513/15, 30(a)

<sup>24</sup> 410 ILCS 50/3(c)

<sup>25</sup> 410 ILCS 305/9

## ILHIE Authority Data Security and Privacy Committee

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- Knowledgeable patient participation in HIE reduces prospect of patient opposition to HIE
- Accommodates participating providers who have voluntarily agreed to grant a specific patient request to limit disclosure of PHI

#### Cons

- Creates additional administrative procedures (and implementation cost) at point of care, but less than under opt-in
- Some specially-protected PHI still requires opt-in
- Some reduction in flow of data to HIE
- Expenditure by HIE required on patient education to inform patients of opt-out choice
- Arguably of little or no interest or material benefit to majority of patients

### *Policy Option: Patients Required to Opt In to Permit PHI delivery through HIE*

#### Pros

- Provides maximum legal protection by providing record of patient permission
- Allows maximum info sharing; all specially-protected PHI can be included in HIE
- Minimizes prospect of conflict with laws of other States to foster inter-State PHI exchange
- Patient's affirmative act of signing increases likelihood of valid consent
- Accommodates HIE's potential secondary uses of data beyond T-P-O

#### Cons

- Potentially significant reduction in patient participation, less data in HIE; can undermine HIE if critical mass not reached
- Expenditure by HIE required on patient education and recruitment to secure sufficient patient participation in HIE
- Creates additional administrative procedures (and implementation cost) at point of care
- Arguably of little or no interest or material benefit to majority of patients

### National Adoption

Opt-Out:	27 States
Opt-In:	12 States
No consent:	3 States
TBD:	8 States

## ILHIE Authority Data Security and Privacy Committee

### Briefing Summary: Policy # 2 (Panel #1) – Data Excluded From v. Hidden at HIE

2. Data Hidden v. Excluded. If a patient exercises a choice against use of the HIE, may the patient's data be collected by the HIE and not disclosed to others, except for mandatory public health reporting, or should the patient data not be forwarded to the HIE?

*Policy Option 1 (Data Hidden from Third Parties): In the event the patient decides NOT to permit data exchange through an HIE, the HIE can receive PHI data, but it cannot be disclosed further without patient consent*

*Option 1a: except for mandatory reporting, e.g. public health*

*Option 1b: except for emergency medical treatment ("break-the-glass")*

*Option 1c: except upon receipt of patient reversal (patient joins HIE)*

*Policy Option 2 (Data Excluded from HIE): In the event the patient decides NOT to permit data exchange through an HIE, HIE cannot receive PHI data.*

*Policy Options 1, 1a, 1b, 1c: Data Hidden from Third Parties, with exceptions*

#### **Pros**

- *Exception 1a:* allows providers to use HIE for submission of mandatory reports to public health authorities
- *Exception 1b:* allows providers to access clinical data required for emergency treatment of the patient
- *Exception 1c:* allows for the HIE to make a more complete longitudinal clinical record to be available for patient treatment once the patient desires to have PHI exchanged through HIE

#### **Cons**

- Patients who desire NOT to have their data exchanged through an HIE due to personal concerns over either (a) harmful potential of information technology and data aggregation, in general, or (b) harmful potential of government access to aggregated data regarding individuals, in general, would not be accommodated