

## ILHIE Authority Data Security and Privacy Committee

### Briefing Summary: Policies # 4, 5 (Panel #5) – Providing and Documenting “Meaningful Choice”

4. Documentation. Can a patient’s decision not to opt-out (i.e., agree to participate in HIE data exchange) be oral, or need it be written? How should patient choice decisions be documented?

5. Meaningful Choice. If patients are provided a choice with regard to the use of HIE for the exchange of patient data, to what extent should the HIE require the provider of health care services to ensure that a patient’s choice is “meaningful” by “discuss[ing] HIE with their patients”?

### Illinois Status Quo

#### *Opt-Out Consent*

The most extensive consideration in Illinois law of the concept of patient opt-out “informed consent” with respect to the personal medical data appears in the Aids Confidentiality Act, which generally provides a patient the opportunity to opt-out of having an HIV/AIDS test conducted<sup>1</sup>. The Act defines “informed consent” to mean:

"a written or verbal agreement by the subject of a test or the subject's legally authorized representative without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion..."

The Act also requires that in order for the patient to be adequately “informed”, the patient must receive “pre-test information”, which “may be provided in writing, verbally, or by video, electronic, or other means”.<sup>2</sup> A provider is required to “document” the patient’s choice.

#### *Opt-In Consent*

The most extensive consideration in Illinois law of the concept of patient opt-in with respect to the personal medical data appears in the Mental Health and Developmental

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<sup>1</sup> AIDS Confidentiality Act, [410 ILCS 305](#).

<sup>2</sup> AIDS Confidentiality Act, [410 ILCS 305/3\(d\)](#). “pre-test information” “entails at least the following..., (1) a fair explanation of the test, including its purpose, potential uses, limitations and the meaning of its results; and (2) a fair explanation of the procedures to be followed, including the voluntary nature of the test, the right to withdraw consent to the testing process at any time, the right to anonymity to the extent provided by law with respect to participation in the test and disclosure of test results, and the right to confidential treatment of information identifying the subject of the test and the results of the test, to the extent provided by law. Pre-test information may be provided in writing, verbally, or by video, electronic, or other means. The subject must be offered an opportunity to ask questions about the HIV test and decline testing. Nothing in this Act shall prohibit a health care provider from combining a form used to obtain informed consent for HIV testing with forms used to obtain written consent for general medical care or any other medical test or procedure provided that the forms make it clear that the subject may consent to general medical care, tests, or medical procedures without being required to consent to HIV testing and clearly explain how the subject may opt-out of HIV testing.”

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Disabilities Confidentiality Act, which includes a number of formal requirements for the validity of a patient authorization.<sup>3</sup>

#### Federal Guidance

##### *Opt-In Consent*

- The Federal HIPAA Privacy Rule currently provides that in circumstances where a written patient authorization for disclosure is required (an “opt-in”), the authorization must be in plain language, revocable and of limited duration (unless for medical research).<sup>4</sup> A covered entity may not condition treatment, payment, enrollment, or benefits eligibility on an individual granting an authorization, except in limited circumstances.<sup>5</sup> A patient’s authorization is invalid if “any material information in the authorization is known by the covered entity to be false”;<sup>6</sup> HIPAA thus does not countenance duress or fraud in the collection of patient consent choices, but the standards by which such aspects of a patient encounter are judged are fairly objective.

##### *Opt-Out Consent*

- In circumstances where HIPAA requires a covered entity to provide an opportunity to object to a disclosure (“opt-out”), HIPAA places no focus on the patient’s subjective state of mind when considering whether to honor a patient’s decision not to exercise an opt-out right. To the extent that patient consent decisions should be subject to external review, HIPAA arguably places reliance on the professional judgment of the covered entities that enjoy a relationship with the patient. For example, in the context of HIPAA’s requirement that patients be provided an opportunity to object (“opt-out”) to certain disclosures, HIPAA provides that the covered entity’s obligation may be satisfied when the covered entity “reasonably infers from the circumstances, based [on] the exercise of

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<sup>3</sup> [740 ILCS 110/3](#), 5. The formal requirements include: • the consent must be in writing and signed by the patient, and the signature shall be witnessed; • the consent shall specify to whom disclosure is made, the purpose for which disclosure is made, and the nature of the information disclosed; • the consent must specify the calendar date of which the consent expires; • “blanket consent” (undefined) to the disclosure of “unspecified information” (undefined) is not valid; • “advance consent” (undefined) is valid only if “the nature of the information to be disclosed is specified in detail” (undefined) and the duration of the consent is indicated.

<sup>4</sup> HIPAA, 45 CFR §164.508(c)(3), (c)(1).

<sup>5</sup> A covered entity may condition the provision of health care solely to generate protected health information for disclosure to a third party on the individual giving authorization to disclose the information to the third party. A covered health care provider may condition treatment related to research (e.g., clinical trials) on the individual giving authorization to use or disclose the individual’s protected health information for the research. HIPAA, 45 CFR 164.508(b)(4).

<sup>6</sup> HIPAA, 45 CFR §164.508(b)(2)(v).

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professional judgment, that the individual does not object to the disclosure”.<sup>7</sup> The concept of “meaningful” choice does not currently appear in HIPAA. The introduction of an undefined subjective “meaningful” qualification upon a patient’s objective “choice” in effect (1) introduces the patient’s subjective state of mind in determining whether an objective exercise of “choice” by the patient is valid, and (2) ultimately shifts to law courts and to external enforcement authorities the overview of the patient consent aspect of patient encounters.

#### *“Meaningful Choice”*

- HHS ONC recently issued guidance to the recipients of HIE planning grants that patients should be provided a “meaningful choice” for participation in a robust bilateral HIE which aggregates clinical data. “... HIE entities should ensure individuals have meaningful choice regarding whether their IHI may be exchanged through the HIE entity.... A patient's meaningful choice means that choice is:
  1. Made with advance knowledge/time;
  2. Not used for discriminatory purposes or as condition for receiving medical treatment;
  3. Made with full transparency and education;
  4. Commensurate with circumstances for why IHI is exchanged;
  5. Consistent with patient expectations; and
  6. Revocable at any time.... Attention should be paid to minimizing provider burden.”
  - In its reply to the ONC, OHIT indicated that it considered such a requirement as “challenging”. OHIT noted the following concerns:
    - Highly subjective. Several of the proposed criteria are highly subjective. Without concrete guidance or objective standards, it would be difficult for an HIE (or the provider at the point of care) to apply to a particular patient encounter the requirement of “full transparency” or to be “consistent with patient expectations”. The lack of objective certainty would be a burden on the provider’s/HIE’s decision making process, resulting in increased costs. Significant additional work is required to advance the concept’s operational implementation.
    - Provider discretion in administrative office matters. As noted above, HIPAA already precludes a covered entity from conditioning treatment or otherwise denying benefits on the receipt from the patient of an

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<sup>7</sup> HIPAA, 45 CFR §164.510(b)(2). Similarly: “A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual’s best interest”, §164.510(b)(3); in disaster relief situations, the covered entity “in the exercise of professional judgment” determines the applicability of patient consent requirements, §164.510(b)(4).

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authorization to send or receive patient data. Providers currently make decisions regarding both administrative office and clinical practice issues without a patient’s involvement in the decisions, which are arguably of greater significance than a provider’s choice of the HIE through which patient data is sent or received.

- Enforcement. The ability of HIEs to “ensure” provider compliance is questionable, at best.

#### *Notice to Patients: Content*

- The Federal HIPAA Privacy Rule currently requires each covered entity, with certain exceptions, to provide a “notice of its privacy practices” (NPP). (Since HIEs are not covered entities, HIPAA currently does not require HIEs to publish a Notice of Data Practices.) The Privacy Rule requires that the notice contain certain elements.<sup>8</sup>
- HHS ONC recently issued guidance regarding the content of the NPP which ONC recommends that be provided by an HIE to patients: “HIE policies should make publicly available a notice of data practices describing why IHI is collected, how it is used, and to whom and for what reason(s) it is disclosed. This notice should be: 1. Simple, understandable, and at an appropriate literacy level....”
  - In its reply to the ONC, OHIT indicated that it considered such a requirement “reasonable”.

#### *Notice to Patients: Delivery*

- The Federal HIPAA Privacy Rule currently requires each covered health care provider with a direct treatment relationship with individuals to deliver a NPP at detailed times at the point of care and electronically on the provider’s website.<sup>9</sup>

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<sup>8</sup> HIPAA, 45 CFR §164.520. The notice must describe the ways in which the covered entity may use and disclose protected health information. The notice must state the covered entity’s duties to protect privacy, provide a notice of privacy practices, and abide by the terms of the current notice. The notice must describe individuals’ rights, including the right to complain to HHS and to the covered entity if they believe their privacy rights have been violated. The notice must include a point of contact for further information and for making complaints to the covered entity. Covered entities must act in accordance with their notices.

<sup>9</sup> HIPAA, 45 CFR §164.520. The NPP must be provided: • Not later than the first service encounter by personal delivery (for patient visits), by automatic and contemporaneous electronic response (for electronic service delivery), and by prompt mailing (for telephonic service delivery); • By posting the notice at each service delivery site in a clear and prominent place where people seeking service may reasonably be expected to be able to read the notice; and • In emergency treatment situations, the provider must furnish its notice as soon as practicable after the emergency abates. Covered entities, whether direct treatment providers or indirect treatment providers (such as laboratories) or health plans must supply notice to anyone

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- HIPAA currently does not require providers to “discuss” (orally) with patients the content of the require notice.
- HHS ONC recently issued guidance that “HIE policies should also encourage health care providers to be open and transparent with patients about their privacy and security practices and to discuss HIE with their patients.”
    - In its reply to the ONC, OHIT indicated that it considered such a requirement as “challenging”. OHIT noted the following concerns:
      - Cost of additional workflow. The proposed “discussion” of HIE with patients represents a significant new workflow requirement at the point of care, whose cost is difficult to quantify but is likely to be very significant. To the extent that onerous obligations are imposed upon providers who join an HIE, providers will face a disincentive to join an HIE, particularly as participation in an HIE is not required for satisfying Stage 2 Meaningful Use.
      - Timing of “individual choice”. The proposed “discussion” of HIE with patients is presumably to occur during a treatment encounter at the point of care, contemporaneously with the collection of relevant patient data and its exchange through an HIE. The timing and location of such a “discussion”, an arguably administrative workflow intrusion at a time when patients present to health care providers to receive medical care, may not be optimal.
      - Enforcement. HIEs can at best require provider compliance with such a requirement as a matter of contract law, and are thus unlikely to have any significant leverage to enforce compliance. Any “damages” to the HIE from such a breach would be speculative, at best, and the prospect of the HIE being able to successfully impose fines or other liquidated damages upon providers is highly unlikely.
  - HHS ONC recently issued guidance that “choice is meaningful (i.e., ...not be limited to, for example, a provider's boilerplate form or reliance on the patient to read material posted on a provider's waiting room wall or website).” The apparent rejection by the ONC of the current HIPAA-approved communication methods represents a material change to current law.
    - In its reply to the ONC, OHIT indicated that it considered such a requirement as “futuristic”. OHIT noted the following concerns:

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on request. A covered entity must also make its notice electronically available on any web site it maintains for customer service or benefits information.

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- Cost of additional workflow. Concerns regarding mandatory provider “discussions” with patients are discussed above.
- Enforcement. Concerns regarding mandatory provider “discussions” with patients are discussed above.

*Policy Option 1: Require participants in HIEs to provide to patients an NPP which includes description of HIE data exchange, but in accordance with current HIPAA requirements and “objective” standards.*

*Policy Option 2: Require participants in HIEs to provide to patients a “meaningful choice” of participation in HIE through delivery of an NPP which includes description of HIE data exchange, and through mandatory individualized “discussion” of the HIE with each patient.*

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### Briefing Summary: Policy # 7 (Panel #5) – Duration of Consent

7. Duration of consent. Should a patient’s choice (either “opt-in” or “opt-out”) be time-limited or of unlimited duration?

#### Federal Guidance

- The Federal HIPAA Privacy Rule currently provides that a patient authorization must bear an expiration date.<sup>10</sup> Most patient data, however, is exchanged without an expiring patient authorization in accordance with the T-P-O exception, and therefore the consent for disclosing most electronic patient data does not have a limited “shelf life”.
- HHS ONC recently issued guidance that “Choice should be offered to each patient on a prospective basis and periodically renewed.” It is unclear whether ONC has proposed that all patient consents be of limited duration.
  - In its reply to the ONC, OHIT indicated that it considered such a requirement as “challenging”. OHIT noted the following concerns:
  - Future release of patient records. HIEs in principle should be able to aggregate all of a patient’s clinical data in order to present a complete longitudinal record. An HIE’s ability to disclose the record at a future date may depend on “re-disclosure” restrictions, which may require that a valid patient consent exist to permit the “re-disclosure”. The imposition of a durational element to a patient consent can create operational difficulties with respect to the future release by the HIE of patient data.

#### Illinois Status Quo

- The Mental Health and Developmental Disabilities Confidentiality Act includes the following durational requirements for a patient authorization to be valid:<sup>11</sup>
  - the consent must specify the calendar date on which the consent expires, provided that if no calendar date is stated, information may be released only on the day the consent form is received by the therapists; and
  - “advance consent” (undefined) is valid only if “the nature of the information to be disclosed is specified in detail” (undefined) and the duration of the consent is indicated.
- The AIDS Confidentiality Act<sup>12</sup> does not contain a durational requirement for a patient authorization, but the implementing regulations of the Department of Public Health specify that the authorization must be “time-limited”<sup>13</sup>, without any further details.

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<sup>10</sup> HIPAA, 45 CFR §164.508(c)(1)(v).

<sup>11</sup> [740 ILCS 110/3](#), 5.

<sup>12</sup> [410 ILCS 305](#)

<sup>13</sup> 77 Ill. Adm. Code 697.140(a)(2).

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### Briefing Summary: Policy # 8 (Panel #5) – Revocation of Consent

8. Revocation of consent. Should a patient's choice (either "opt-in" or "opt-out") be subject to revocation?

#### Federal Guidance

- The Federal HIPAA Privacy Rule currently provides that a patient authorization must be revocable.<sup>14</sup>
- HHS ONC recently issued guidance that "... A patient's meaningful choice means that choice is: ...6. Revocable at any time."
  - In its reply to the ONC, OHIT indicated that it considered such a requirement as "reasonable", but noted the following concerns:
  - Additional functionality. To be able to accept and track patient revocations, most HIEs will presumably need to acquire and maintain the equivalent of a patient consent revocation registry, for which necessary implementation resources presumably have not been anticipated.
  - Policy – conflicting patient choices. To operationalize "individual choice" including revocation rights, HIEs will need to adopt policies that reconcile conflicting patient choices expressed to different participants in the network; statutory amendments may be required.

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<sup>14</sup> HIPAA, 45 CFR §164.508(c)(2)(i).