REPORT ON FEEDBACK RECEIVED ON CONSENT GUIDING PRINCIPLES

Prepared for:
Connecticut Office of Health Strategy (OHS)
Connecticut Health Information Technology Advisory Council (HITAC)
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DRAFT Consent Guiding Principles, developed by the Consent Design Workgroup and affirmed by the Health IT Advisory Council in December 2019, were posted on the OHS website on February 14, 2020 along with background and a request to provide feedback by March 15, 2020. Emails were sent with background information and a request to provide input by March 15, 2020 to all OHS Listservs (450 subscribers) and to the OHS Newsletter Listserv (609 subscribers). A copy of the background information and request for input is attached as Appendix A to this report

A total of 10 submissions were received during the feedback period: six from individuals, not representing the interests of an organization, one from Universal Health Care Foundation, one from Health Equity Solutions, one from the Connecticut Health Policy Project, and one from the Connecticut Hospital Association. The feedback ranged from general support for, or general opposition to, the proposed Guiding Principles. Some submissions included very specific questions and detailed feedback regarding one or more of the Guiding Principles, and several submissions provided viewpoints on risks as well as benefits of electronic health information exchange in general.

Common themes of feedback:

- Guiding Principles do not address the monetization of patient data;
- Guiding Principles should be more reflective of a patient-centric approach;
- Guiding Principles should speak more specifically to data security;
- Guiding Principles do not address the opportunity to opt-in or out-out of having data shared across the HIE platform.

Although not directly responsive to the Guiding Principles, a number of submitters offered concerns regarding the member composition of the HITAC, suggesting more attention is needed to ensure the racial and ethnic makeup of the Council is more representative of the diversity of Connecticut residents. Along with that input, some submitters expressed the view that HITAC should have more consumer/patient members among its ranks.

Analysis of comments received:

The feedback received was assessed based on the following rubric:

1. Does the comment address a Guiding Principle?
2. If yes, does the comment address an issue regarding a Guiding Principle that was not considered during the Consent Design Group process and/or HITAC deliberations?
3. If yes, would the issue raised by the commenter be best addressed by additional HITAC discussion or would the issue be better suited to consideration during the consent policy development process?

4. If no, how might HITAC and OHS ensure the comment is given consideration in the appropriate context and by the appropriate groups and/or individuals?

Each submission was analyzed against the rubric. In many cases, the Consent Design Group and HITAC meeting minutes and recordings were reviewed to answer question #2 of the rubric, with particular attention on whether the input was thoroughly vetted during the process of developing the Guiding Principles. An additional level of analysis was applied to all submissions by weighing rubric question #3, as the Guiding Principles are intended to be the beginning of consent policy development in Connecticut, not the policies themselves. These assessments were done individually by CedarBridge consultants, and then compared, with the goal of reducing the potential for "group think" bias. This assessment process resulted in the recommendation HITAC affirm the Guiding Principles as written and refer the relevant feedback to the Office of Health Strategy as the government agency charged with developing consent policies for specific purposes of data use and data exchange.

Specific feedback received:

Recommendation 1
Consent policies should require patients be provided clear and detailed information about health information sharing choices under applicable State and Federal law.

Recommendation 2
Consent policies should require Connecticut's Office of Health Strategy to develop an educational resource tool kit on health information sharing, leveraging and adapting content from recognized third-party resources. Educational content should be reviewed and approved by the Health IT Advisory Council, and should not only include information for patients, parents and guardians, but also for providers, pharmacies, labs, health plans, state and local government agencies, and employers. The information should be translated for non-English speakers and should conform to the Web Content Accessibility Guidelines developed by the Web Accessibility Initiative (WAI), part of the World Wide Web Consortium (W3C).

Recommendation 3
Information and educational resources on consent policies should be distributed broadly throughout Connecticut and be made widely available and easily accessible through a variety of sources including the Health Information Alliance, all health and human services agencies and departments in the state of Connecticut, and organizations participating in HIE services in Connecticut. The distribution process will be supported by HIA's partners, including the Office of Health Strategy (OHS).

- Three specific submissions were received on Recommendations 1 – 3. The theme of the feedback focused on specifying specific populations and including criteria for educational resources such as meeting health literacy guidelines.

Recommendation 4
A review of consent policy considerations should be conducted for each HIE use case before an HIE use case is put into production, with a use case-specific consent policy developed if indicated from the review.

- One submission in agreement with Recommendation 4 was received.

Recommendation 5
Notification of a healthcare organization's participation in electronic health information exchange(s) should be included in the Notices of Privacy Practices (NPP).

- One submission disagreeing with Recommendation 5 was submitted, stating that "requiring amendments to existing NPPs is an unnecessary step that will create cost and administrative burdens for providers".

Recommendation 6
Consent policies should result in the lowest possible burden on providers responsible for their implementation and maintenance, without compromising the need for sufficient patient understanding and ability to exercise meaningful consent.

- Three submissions spoke to Recommendation 6; one in favor, one opposed, and one asking for additional language.
    - It was noted by one submitter that this Guiding Principle acknowledged the additional burden placed on providers to implement consent yet does not recognize the history of coercive practices targeted toward communities of color in the medical setting.
    - It was suggested to add a requirement for providers to engage in training that supports integrity in the consent process.
    - One submission opposed to this Guiding Principle noted the recommendation does little to address the issue of what constitutes the standard a provider must meet for an effective and meaningful consent process.

Recommendation 7
Clearly written information about consent policy changes should be provided to patients, parents and guardians, state and local health and human service agencies, and all licensed healthcare entities in a timely manner when policies or practices have changed, adhering to the principles of broad dissemination and accessibility of information described above.

- One submission was received supporting this recommendation however, the commenter cautioned changes in policy will be difficult to administer with previously obtained consents.

Recommendation 8
Mechanisms, including paper based and digital tools, for expressing consent policy preferences should be user-friendly and easily accessible.

- One submission was received supporting ease of use for providers, carriers, and patients; however, the submission also cautioned that expectations for managing consents (including retention, linking to patient and consumer records, and security for digital versions) should be given careful consideration, advising the use of existing systems and tools to help avoid added costs and/or administrative burdens.

Recommendation 9
Consent policies should explain clearly and completely what happens if a patient revokes consent, including what happens with patient data and their previously expressed consent.

- One submission was received supporting clear messaging to patients and consumers about consent and revocation of consent. The submission also recommended for the State HIE to adopt an opt out process. It noted the term "revocation" may not adequately describe the process of opting out because the initial consent would be passive consent (subject to a future opt out).
- The submission urged specific, clear communication be included in educational materials about state mandated health data reporting systems, for which patients have no consent rights or ability to opt out. This would include, for example, the Connecticut Prescription Monitoring and Reporting System (often called the PDMP), or communicable disease reporting to DPH.
- The submission also urged careful consideration be given to the differences between passive consent (or opt out) versus fact patterns (or use cases) that would require a HIPAA-compliant authorization pursuant to 45 CFR 164.508. As the State HIE use cases are not yet known, the submission noted it is not obvious whether some use cases might require a HIPAA-compliant authorization.

Recommendation 10
Third-party vendors and contractors supporting HIA, Inc. in its health information exchange activities should be contractually bound by HIA, Inc. to abide by the consent policies of HIA, Inc.

One submission was received stating that vendors and contractors should be made aware of, and required to comply with, applicable consent policies set by the State HIE. The submission also noted that this presupposes that all policies are consistent with state and federal law, including HIPAA.

Recommendation 11
Consistent with federal and state law, including but not limited to HIPAA, consent policies should require safeguards be followed consistent with the responsible stewardship associated with protection of a patient's health information against risks such as loss or unauthorized access, use, alteration, destruction, unauthorized annotation, or disclosure.

- One submission called out the varied roles of the State, State HIE, covered entities, and business associates and advised that consent policies will need to provide specific language to address the various roles and responsibilities.

Recommendation 12
Consent policies shall address sensitive and specially protected data in alignment with federal and state statutes, as may change from time to time.

- Two submissions were received addressing the need to be especially careful when establishing policy for specially protected data. One of the submissions suggested a principle addressing possible compromises in data security with respect to marginalized communities, given our national history of taking the health information of and engaging in untested health practices on marginalized communities without consent.

Recommendation 13

Consent policies should be aligned with certain national interoperability initiatives, including the Common Agreement (CA) under development as part of Trusted Exchange Framework and Common Agreement (TEFCA), to support the ability to exchange data with entities outside the state.

- One submission was received supporting this recommendation however, also cautioned that adopting optional requirements should only be done after careful consideration of the capability of providers and others to comply without added costs or burden.

Recommendation 14

Consent policies should be reviewed periodically to ensure it is aligned with these principles and complies with any changes in best practices or federal or state law.

- One submission was received supporting this recommendation and cautioned that substantive changes should be made only when necessary because changes to the consent policy or process will cause disruption for data capture, and increase operational expenses for the State HIE and participants.

Recommendation 15

Consent policies should provide a clear procedure for addressing complaints by individuals regarding the use of their data.

- Two submissions were received addressing this recommendation. One submission suggested the process be transparent and timely.
- The second comment pointed out covered entities cannot delegate or avoid federal obligations under the HIPAA breach notification rules set forth in 45 CFR 164.400-414.

Recommendation 16

Consent policies should require that patients have ample opportunity to review educational material before making a consent decision.

- One submission was received supporting this recommendation but cautioned that implementing a process that requires express feedback from patients other than at point of care is difficult. Patients will be at point of care only episodically, and for many patients, infrequently.

Recommendation 17

Consent policies should require a consent decision is not used for discriminatory purposes.

- Two submissions were received supporting this recommendation.
- One shared that patients should be told that there will be times that a decision to opt out of participation might affect how organizations, agencies, and other providers can assist them.
- The second submission suggests a rewording of the recommendation to make it read less awkwardly.

Recommendation 18

Assessments should be made periodically to ensure patients understand their health information sharing choices.

- One submission was received supporting this recommendation and urged that assessments be designed in a way that creates little or no burden for providers and patients.

Recommendation 19

Transparency and stakeholder input are foundational to the development of meaningful consent policies. While the HIA, Inc. Board has responsibility for overall governance of its health information exchange services, consent policy development should be led by the Office of Health Strategy (OHS), and advised by the Health IT Advisory Council. The process proposed is as follows:

a) The Health IT Advisory Council should draft, review and approve consent policies for the health information exchange that are conformant with these Guiding Principles and State and Federal law;
b) The Health IT Advisory Council may choose to convene ad hoc or standing work groups to support consent policy development;
c) Once consent policies have been endorsed by the Health IT Advisory Council, OHS should review the recommendations and determine any necessary statutory or regulatory actions that may be required;
d) HIA, Inc. will be responsible for the implementation and maintenance of consent policies adopted by the State through OHS policy, statute or regulation;
e) Should HIA, Inc. have concerns about any consent policies received from OHS, it may request a meeting with OHS to resolve those concerns; such resolution may require a review of proposed changes by the Health IT Advisory Council;
f) All meetings of the Health IT Advisory Council are open to the public and the public is provided an opportunity to make comments at each meeting, including comments related to consent policies;
g) All board meetings of the HIA, Inc. are open to the public; and
h) Draft consent policies should be made available for a 30-day public comment period. In addition, an in-person session for public review and comment regarding draft consent policies may be considered prior to approval by the Health IT Advisory Council. The Health IT Advisory Council should review and consider recommendations or comments from the public to determine whether revisions to policies should be made.

- One submission was received noting pursuant to Section 17b-59e(b) of the Connecticut General Statutes, hospitals and laboratories are mandated to *participate* in the State HIE.
- The same submitter also noted that steps a hospital or lab must meet to be compliant with the mandatory participation clause in Section 17b-59e are still unknown.

All input will be preserved and shared with OHS for discussion and evaluation during the consent policy development process. Pursuant to OHS policy, each submitter will receive a response to their submission. Questions posed in submissions will be answered in these responses. The responses will be posted on the OHS website. A compilation of the questions posed in the feedback are included as Appendix B to this report.

APPENDIX A

OHS Seeks Feedback on DRAFT Consent Guiding Principles

The Office of Health Strategy (OHS), guided by the Connecticut Health IT Advisory Council, provides contractual oversight of the Health Information Alliance, Inc. (HIA), Connecticut's newly formed statewide health information exchange (HIE) entity. In coming months, HIA will begin offering services to connect existing data systems and to further enable the exchange of health information between providers and healthcare organizations, and with the individuals they care for.

In preparation for the launch of HIA's data exchange services, the Health IT Advisory Council recommended OHS convene a Consent Design Group to develop a framework on which the HIA's consent policies will be approached. The Consent Design Group's work occurred over thirteen meetings from April through November of 2019.

The Consent Design Workgroup developed an extensive set of DRAFT Guiding Principles for OHS to use as foundational tenets for establishing future consent policies, and for evaluating technical solutions for consent management that may be offered by HIA to participants in statewide health information exchange. The Health IT Advisory Council, comprised of public and private sector leaders appointed by Connecticut General Assembly leadership and by Governor Lamont and former Governor Malloy, also contributed to the DRAFT Guiding Principles, providing a thorough review and recommending changes to OHS during several meetings between November 2019 and January 2020. The Final Report and Recommendations of the Consent Design Workgroup, contain the DRAFT Guiding Principles as well as the background and details of the Consent Design Workgroup's process and work.

OHS is seeking feedback on the DRAFT Guiding Principles through March 15, 2020. All feedback submitted through this process will be documented and presented to the Health IT Advisory Council at their March 19, 2020 meeting. Following the Health IT Advisory Council's review of all feedback submitted through this process, next steps will be determined in order for OHS to finalize the Guiding Principles and begin to consider specific consent policies for various types of data, and various purposes for data exchange.

Please submit all feedback on the DRAFT Guiding Principles, and any additional input to help inform future planning for consent policies to HITO@ct.gov.

APPENDIX B

QUESTIONS POSED IN FEEDBACK TO CONSENT GUIDING PRINCIPLES

Guiding Principles 1, 8, 9, and 16:

- How will the Guiding Principles address the March 9, 2020 HHS rulings that further empower the patient consumer over their healthcare records?
- What will be the default setting for patient participation – 'opt-in' or 'opt-out'?

Guiding Principles 4, 5, 11, 12, and 13:

- How will the Guiding Principles address Patient Access API, Provider Directory API, Payer-to-Payer Data Exchange, Dual Eligibility Data Exchanges, Public Reporting and Information Blocking, Digital Contact Information, and ADT (Admission, Discharge, and Transfer Events) Notifications.

Guiding Principles 5, 11, 12, and 13:

- How will the Guiding Principles address the privacy concerns?

Guiding Principles 5, 7, 8, 10, 11, 12, 13, 18, and 19:

- How will the Guiding Principles address the concern of utilization and monetization of the patient consumer data?
- Can the patient consumer completely opt-out of the utilization and monetization of their data?

Guiding Principle 10:

- To what extent will third-party vendors and contractors supporting HIA Inc. be required and/or expected to follow (i) state contracting rules and (ii) state ethics rules in light of the fact that the HIA is "acting on behalf of the state." Conn. Gen. Stat. § 17b-59a. The form and format of the terms of required business associate contracts may be affected by these rules.

Guiding Principle 19:

- Recommendation 19 describes various process steps that OHS and the Health IT Advisory Council will take to ensure development of the consent policies for the State HIE. To what extent are those steps, and the final consent policies that result, subject to due process and administrative procedures applicable to state agencies?

- To what extent are actions and decisions of HIA subject to due process and administrative procedures applicable to state agencies?