FINAL REPORT AND RECOMMENDATIONS OF THE CONSENT POLICY DESIGN GROUP

November 2019

Report prepared for: Health IT Advisory Council

Prepared by:

Carol Robinson, *CedarBridge Group*

Michael Matthews, *CedarBridge Group*

Sheetal Shah, *CedarBridge Group*

CedarBridge Group LLC
515 NW Saltzman Rd. #661
Portland, OR 97229
www.cedarbridgegroup.com

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Acknowledgements

On behalf of the State of Connecticut, the Executive Director of the Office of Health Strategy and the Health Information Technology Officer express their sincerest gratitude to all those who served on the Consent Design Group, as well as those who supported the work of the group. Your insights, perspectives, and wisdom were invaluable in the development of recommendations for Guiding Principles for consent policy development and are a testament of your desire to help improve the health and well-being of the citizens of Connecticut.

Introduction

The Consent Policy Design Group, created and sponsored by the Health IT Advisory Council, is comprised of volunteer stakeholders representing a wide range of subject matter expertise from across the healthcare industry. The Design Group conducted a broad review and analysis of existing consent policies and regulatory requirements, both within Connecticut and at the national level, and assessed the policy implications and considerations applicable to statewide health information exchange. This Final Report and Recommendations provides a solid foundation upon which future consent policies can be developed.

Project Structure and Process

Role of Consent Design Group

The Health IT Advisory Council charged the Consent Design Group with the responsibility for recommending an initial approach to patient consent and an ongoing structure and process for evolving the consent model as health information exchange in Connecticut matures and expands over time.

The original objective was to develop a draft consent policy to address data sharing and data use requirements for the initial use cases planned for early-stage implementation by the statewide health information exchange, Health Information Alliance, Inc. (HIA). This objective was modified during the Consent Design Group discussions when the formation of HIA was delayed from the expected timeframe of early 2019 to late summer.

With the HIA technical architecture and legal framework still evolving during this period, the Design Group was lacking enough specificity on the initial use cases to achieve the original objective. The modified objective was to create Guiding Principles to support consent policy development, rather than creating consent policy language. Focusing on Guiding Principles was deemed to be more aligned with the current state of use case implementation. Furthermore, the principles would not only support initial use cases, but apply to the consideration of future use cases as well.

Consent Design Group Members

The members of the Consent Design Group provided subject matter expertise and represented a broad array of stakeholder perspectives across the health care ecosystem. Members are as follows:

Table 1: Consent Design Group Members

Name	Affiliation and Role
Stacy Beck	Anthem, Clinical Quality Program Director
Pat Checko	Consumer Advocate
Carrie Gray	UConn, Director of Information Security, HIPAA Security Officer
Susan Israel	Patient Privacy Advocate
Rod Rioux	CHCACT, Network Director

Rachel Rudnik	UConn, AVP, Chief Privacy Officer
Nic Scibelli	Wheeler Clinic, CIO

Consent Design Group Process

The Consent Design Group's work occurred over thirteen meetings from April through November of 2019. The first two meetings provided members with background information and context to establish a common understanding of goals, objectives, terminology, and relevant information. Meetings three through five were discussions focused on the Health Information Exchange (HIE) use case approach and trust framework. The remaining meetings were devoted to enhancing the members' understanding of Connecticut's plan for HIE implementation and the review and discussion of Guiding Principles supporting consent policy development.

Table 2: Consent Design Group Meeting Schedule

Meeting Goal and Focus
Meeting #1 (April 9, 1pm-2pm) Kick-off and Orientation
Meeting #2 (April 23, 1pm-2pm) Current Consent Policies
Meeting #3 (May 7, 1pm-2pm) Use Case Approach to Sharing Data
Meeting #4 (May 21, 1pm-2pm) Use Case Approach to Sharing Data (Part 2)
Meeting #5 (June 4, 1pm-2pm) Roadmap to Final Consent Recommendations and Patient Provider Identity Care Map Function
Meeting #6 (June 18, 1pm-2pm) Disclosure Notification Policy Draft Review
Meeting #7 (July 9, 1pm-2pm) Disclosure Notification Policy Draft Review and Update
Meeting #8 (July 23, 1pm-2pm) HIE Governance and Likely Initial Use Cases
Meeting #9 (September 17, 1pm-2:30pm) HIE Governance and Likely Initial Use Cases (Part 2) & Guiding Principles Introduction
Meeting #10 (September 24, 1pm-2:30pm) Review Guiding Principles
Meeting #11 (October 15, 1pm-2:30pm) Review Guiding Principles

Meeting #12 (October 29, 1pm-2:30pm) Finalize Guiding Principles
Meeting #13 (November 12, 10am-11:00am) Review and Finalize Final Report & Recommendations

Consent Design Group Guiding Principles

Recommended Guiding Principles

The majority of Design Group members came to consensus on a set of Guiding Principles which they recommend be used when developing consent policy specific to any current or future HIE use cases. In this context, the Guiding Principles are a set of core tenets that establish a framework for consent policy development. They lay the foundation for consent policy development long-term and should be effectively communicated and referenced by all organizations and individuals involved in consent policy development.

With a subject matter as complex and nuanced as consent, a range of perspectives are to be expected. While the recommended Guiding Principles represent the views of the majority of Consent Design Group members, all members were invited to add their individual perspectives and comments on the Guiding Principles for consideration by those involved in consent policy development in the future. This can be found in Appendix A: Additional Considerations and is hyperlinked under the respective principle.

The Guiding Principles address a range of topics, including, but not limited to, patient education and dissemination, consent revocation, transparency and process for stakeholder input, and limiting provider burden.

Please find the full set of Guiding Principles below:

Guiding Principles
Recommendation 1 *Consent policies should require patients be provided clear and detailed information about health information sharing choices under applicable State and Federal law.* • Please refer to Additional Considerations for further comments on this Guiding Principle from one or more Design Group members.
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.[1] Educational content should be reviewed and approved by the Health IT Advisory Council, and*

[1] Adapted, with permission, from the CARIN Alliance Trust Framework and Code of Conduct (https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/)

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[2] developed by the Web Accessibility Initiative (WAI), part of the World Wide Web Consortium (W3C).[3]

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).

Recommendation 4

A review of consent policy considerations should be conducted by appropriate subject matter experts 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.

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).

- Please refer to Additional Considerations for further comments on this Guiding Principle from one or more Design Group members.

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.

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.

Recommendation 8

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

- Please refer to Additional Considerations for further comments on this Guiding Principle from one or more Design Group members.

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.

[2] https://www.w3.org/WAI/standards-guidelines/wcag/
[3] https://www.w3.org/WAI/

Recommendation 10

Consistent with federal and state law, including but not limited to HIPAA, consent policies should require third-party vendors and contractors be contractually bound by Business Associate Agreements (BAAs) to publish privacy policies of any organization facilitating electronic health information exchange in Connecticut, and prohibit use or disclosure of patient information (including de-identified, anonymized or pseudonymized data) for any undisclosed purposes without express consent from the patient.

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.

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.

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.

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.

Recommendation 15

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

Recommendation 16

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

Recommendation 17

Consent policies should require a consent decision is not used for discriminatory purposes or as condition for receiving medical treatment.

Recommendation 18

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 prior to approval by the Health IT Advisory Council and the Health IT Advisory Council should review and consider recommendations or comments from the public to determine whether revisions to policies should be made.*

- Please refer to Additional Considerations for further comments on this Guiding Principle from one or more Design Group members.

Conclusion

Federal and state regulations, policies, and guidelines for electronic health information exchange including privacy and security protections are continuing to evolve and mature. As part of the evolution, consent policies, whether set by organizations or by government entities, will continue to be debated, reviewed, updated, or revamped, as was the case recently when the 2019 Vermont legislature voted to revise state statute and move Vermont from “opt-in” to “opt-out” for HIPAA-related data exchange. Likewise, technical solutions for managing consent preferences will also undoubtedly mature to ensure the value of health information exchange is maximized and patient’s rights to privacy and confidentiality are protected.

The Guiding Principles developed by the Consent Design Group will provide structured guidance to stakeholders from all sectors, including consumers, who are engaged in future policy planning. The Guiding Principles should also serve as a basis for meaningful evaluation of policies and technologies that will provide individuals with more choice and more control over how their health data is shared and used.

Appendix A

Additional Considerations

Please find below additional considerations that were associated with four of the Guiding Principles:

- In reference to Guiding Principle 1:
  - Patients must be allowed to opt-out of the HIE completely. If not, it must be clearly stated which of their data will be included in the HIE without their express consent, because this can be allowed by the HIPAA business associate agreements. Such data may include their identifiers for matching to providers and identified medical information shared between providers and with OHS for public health, tumor registry, discharge summaries, quality measures, CDAS, etc.

- In reference to Guiding Principle 5:
  - Health care organizations should also provide patients with the location of where they can find more information on which HIEs providers participate in.

- In reference to Guiding Principle 8:
  - Regardless of what consent methodology is in place (e.g., opt-in or opt-out), the mechanisms for expressing consent preferences should also provide clear information regarding the impact and consequences of the consumer's choice.

- In reference to Guiding Principle 18:
  - Consent policies should be decided in the public domain and accepted by the Regulations Review Committee. In preparation for drafting the consent policies for the LRRC, OHS/HIT Advisory Council should hold hearings on the proposed consent policies to be held at the Legislative Office Building with notice in the Legislative Bulletin, along with a well-publicized, written input process for each consent policy and the public posting of all comments. Additionally, bi-annual hearings should be held to review the consent policies and their efficacies. This is needed to ensure that the public has some control over who sees their medical information. Otherwise, OHS may be able to put data into the HIE without patient consent, as allowed by HIPAA for treatment, payment and health care operations.

Appendix B

Meeting Materials

Meeting	Meeting Materials
Meeting #1 (April 9, 1pm-2pm) Kick-off and Orientation	• Agenda • Minutes • Additional materials
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