



**Office of Health Strategy Recommendations  
Regarding the  
Statewide Health Information Exchange  
Consumer Consent Policy Public Comment Summary  
and  
Five-year Health Information Technology Environmental Scan**



**17b-59d**  
**Statewide Health Information Exchange**  
**Consumer Consent Policy Public Comment Summary**  
**and**  
**Office of Health Strategy Recommendations**

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## **Introduction**

On April 26, 2021, the Office of Health Strategy (OHS), consistent with Conn. Gen. Stat. § 17b-59a(c), posted the draft consent policy for patient consent in the statewide health information exchange (HIE) seeking public comment about and recommendations for revisions to the draft. The comment period was open for thirty (30) days, and we received eleven (11) responses. This consumer engagement represents a fundamental element in the development of this policy in order to facilitate consideration of and, where appropriate at this time, inclusion in this draft.

In addition, pursuant to Conn. Gen. Stat. § 17b-59a(c), OHS is also tasked with our review of state-wide health information technology plan (Plan) to “establish electronic data standards to facilitate the development of integrated electronic health information systems for use by health care providers and institutions that receive state funding.” As an integral element of this complimentary initiative, OHS engaged stakeholders to develop an HIT Environmental Scan Report for input and recommendations concerning this review of the Plan. OHS is currently drafting recommendations for revisions to the Plan based on this feedback and, given the relevance of this initiative to the development of the patient consent policy recommendations, have included a summary of the key findings of the scan.

## **Section 1 Purpose**

Pursuant to Conn. Gen. Stat. § 17b-59a(c), the Office of Health Strategy “shall establish electronic data standards to facilitate the development of integrated electronic health information systems”. Conn. Gen. Stat. § 17b-59f further designates the Health Information Technology Advisory Council (HITAC) to advise the Office of Health Strategy “in developing priorities and policy recommendations for advancing the state's health information technology and



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health information exchange efforts and goals and to advise the executive director and officer in the development and implementation of the state-wide health information technology plan and standards and the State-wide Health Information Exchange, established pursuant to Conn. Gen. Stat. § 17b-59d. The advisory council shall also advise the executive director and officer regarding the development of appropriate governance, oversight and accountability measures to ensure success in achieving the state's health information technology and exchange goals.”

This Policy represents the HITAC’s recommendations for the principles and standards that the Health Information Alliance, Inc. (HIA), the program established pursuant to Conn. Gen. Stat. § 17b-59g, should incorporate into the policies and procedures of the State’s health information exchange (HIE) regarding patient consent. These policies and procedures must include identification of key Federal, including but not limited to Health Insurance Portability and Accountability Act (HIPAA), and State law and regulations that govern access to or the release of Protected Health Information (PHI) and safeguards to ensure the security and proper use of patient PHI for the purposes set forth in Conn. Gen. Stat. § 17b-59d. The HIA should ensure that consumers are informed about the goals of the HIE, the benefits of participating in the HIE, and the member’s right to limit sharing of their PHI.

## **Section 2 Scope**

- (1) Policy Statement
  - (a) The default consumer consent policy for the state’s HIE is opt-out. This means that a consumer must proactively, and explicitly, declare their desire not to permit their PHI to be included in the HIE. Opting out means that a consumer’s PHI may no longer be returned as the result of a query or sent as



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an encounter notification. Opting out does not affect or alter a provider's use or disclosure of their patient's PHI in Direct Messaging or other permitted uses and disclosures under applicable state and federal law.

- (b) With respect to sensitive and/or specially protected health information, the default consumer consent policy for the HIE is Affirmative Consent, as set forth in state or federal law, including but not limited to 42 C.F.R. Pt 2. This means that a provider may not disclose consumer sensitive and/or specially protected health information to or through the HIE without Affirmative Consent from the patient or the patient's legally-authorized personal representative.

### **Section 3 Opt-Out Process**

- (1) The HIE shall not disclose a patient's PHI if the patient or the patient's legally-authorized personal representative has affirmatively elected to withdraw the default consent to their PHI being accessible via the HIE pursuant to the process set forth in this section. A consumer who affirmatively opts-out of participating in the HIE in the manner set forth herein will not have their PHI shared, returned as the result of a query or sent as an encounter notification.
- (2) The HIE is responsible for the maintenance of consumer consent preferences, enabling consumers to update their consent selections at will, and shall provide:
  - (a) a dedicated webpage for consumers to receive information about their consent options and processes;
  - (b) methods for consumers to make a consent decision including,



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but not limited to:

- i. an online consent designation form,
- ii. a toll-free telephone number, and
- iii. a paper consent designation form, which shall include a clear description in plain language consistent with CLAS standards including, but not limited to, the following elements:

1. describing the consumer's rights;
2. the consequences of opting-out of participating in the HIE;
3. the known uses of the consumer's information within the HIE, as may change from time to time;
4. examples of common use cases, per Section 5 of this policy, that the consumer's information may be used for by the HIE and their health care provider.

- (c) consumers with confirmation of their consent preference including, but not limited to:

- i. the consumer's: name, date of birth, unique consumer identifier, as applicable;
- ii. consent preference(s) and limitations to access;
- iii. the date the consumer made the selection;
- iv. expected date the selection will be active in the consumer's record in the HIE; and
- v. a listing of available customer service and technical assistance contact options.

- (3) The HIE must process each request to modify a consumer's consent preference so that it is reflected in the HIE as soon as practicable,



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except that such request shall be processed no later than thirty (30) days after receipt of consent selection.

(4) Exceptions to Disclosure of PHI

(a) For patients participating in the HIE, the HIA may use and disclose a patient's PHI as permitted by applicable law and consistent with HIA policy. The consent selection principles and standards set forth in this Policy shall not apply to the following functions and activities:

- i. Direct messaging, by which the health information exchange may transmit a patient's PHI from one participating provider to another participating provider involved in that patient's treatment;
- ii. Reporting of PHI by the HIA for public health purposes and access to PHI by public health authorities, consistent with HIA's review and Board approval of any such request;
- iii. Access to or the disclosure or receipt of PHI for the proper management and administration of the HIE or to carry out the legal responsibilities of the HIE, including but not limited to performing system maintenance, testing, and troubleshooting and providing operational and technical support; and
- iv. Use and disclosure of PHI required by law.

(5) Electronic Signatures

(a) Consumer signatures may be obtained electronically provided that there is an electronic signature consistent with 15 U.S.C. § 7001 et seq., or any other applicable state or federal laws or regulations.

(6) Durability



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- (a) A patient's opt-out preference selection and a patient's Affirmative Consent shall remain in effect unless and until consumer expressly changes the preference or Affirmative Consent in a manner defined in this Policy.
- (7) Revocability
- (a) Consumers may opt-out of the HIE or revoke their affirmative consent at any time provided that such opt-out or revocation shall not preclude any provider that has received PHI via the HIE prior to such opt-out or revocation and incorporated such PHI into its records from retaining such information in its records, subject to applicable state and federal law.
  - (b) For consumers that chose to opt-out or revoke their affirmative consent, the HIA may retain the minimum necessary patient identifying information to identify the patient in the HIE for the sole purpose of capturing their consent choice. The minimum necessary patient identifying information retained will be the: i) Patient's first and last name, ii) phone number, iii) date of birth and iv) address.

#### **Section 4 Consumer Engagement**

- 1) The HIA shall develop a consumer engagement plan and a policy based on such plan to share with participating providers, which shall provide their patients with information concerning their consent options, including but not limited to:
  - i. a description of the processes established by the HIE;
  - ii. a statement in plain language explaining their consent options and consequences of opting-out; and
  - iii. staff support for consumer questions.
- 2) The HIA shall ensure that its consumer engagement and outreach policy:





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- i. describes how the HIE will safeguard consumers' PHI consistent with state and federal law;
  - ii. describes the possible uses of the data sent to the HIE, including, but not limited to, exemptions from affirmative consent (disclosures required by law, for public health purposes, etc.) or use cases for which the HIE may collect fees for authorized access to the data.
  - iii. is promoted and distributed broadly throughout the state;
  - iv. easily accessible to all consumers, with accommodation and materials available in the top fifteen most prevalent languages spoken in the state; and
  - v. accounts for health and social inequities and social determinants of health.
- 3) Consumers must be provided with information on where to file a complaint if they feel their PHI was used without their consent, including the HIE's policy detailed process on how such complaints will be investigated and addressed, including any rights of appeal.
- 4) Patient Access to Data Access logs is an integral element of the HIE. Consistent with the goals set forth in Conn. Gen. Stat. § 17b-59d, patients must have access to their records in the HIE, as well as an accounting upon request of who has accessed their PHI. HIA shall ensure that patients clearly understand that options for requesting this accounting.<sup>1</sup>
- 5) The HIE shall provide a means for communicating to consumers current information about updates to this policy in clear and plain language, consistent with CLAS standards.

## Section 5 Use Cases

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<sup>1</sup> Consumers can fill out an Accounting of Disclosure Request Form on HIA's website. [https://connectnew.wpengine.com/wp-content/uploads/2021/03/AoD-Request-Form-Connie\\_Fillable.pdf](https://connectnew.wpengine.com/wp-content/uploads/2021/03/AoD-Request-Form-Connie_Fillable.pdf)



- 1) HIA shall promote transparency with respect to proposed and implemented HIE use cases. In furtherance of such transparency, HIA shall develop and implement consumer engagement plans and policies to clearly inform consumers about additions, updates or revisions to the HIE's use cases, and to make details about use cases and related information accessible to the public, such as by posting information about use cases and descriptive examples in plain language on HIA's public-facing website. HIA recognizes that a key principle of use case transparency is a thoughtful and accessible consent process.
- 2) As a fundamental element of HIA's design and development of any use case, the HIA shall evaluate the specific consent requirements and process for each use case and address the impact of applicable state and federal law on the proposed use case.

## **Section 6 Miscellaneous Provisions**

- 1) The ONC 21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (CURES) prohibits "information blocking" which is a practice engaged in by an Actor that interferes with the access, use or exchange of Electronic Health Information (EHI). The United States Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) is responsible for oversight of information blocking and has issued regulations to provide details on what constitutes information blocking (the Information Blocking Rule (IBR)). The IBR includes important definitions about who is subject to the CURES information blocking provisions, what constitutes a violation and what steps those subject to the information blocking provisions can take to protect themselves from enforcement. A comprehensive discussion of the IBR is beyond the scope of this document but since HIA is an Actor under the IBR as a Health Information Network (HIN), HIA intends to develop policies and procedures to ensure compliance and conformance



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with the IBR. It is important to note that the IBR does not negate HIPAA. Indeed, ONC has made very clear that the IBR and HIPAA are meant to work together to promote the access, use or exchange of information while still protecting the privacy and security of ePHI and other sensitive information.

**OHS Draft Consent Policy Recommendation Public Comment Notice**

A copy of the OHS Draft Consent Policy Recommendation, with a 30-day (4/26-5/26) notice to submit public comment was posted on 4/26 to the OHS website ([here](#)), and an email notification was distributed to the OHS listserv (which includes all OHS workgroups) for this opportunity. Over the 30-day period, the following comments (copied directly from email or appended herein) were received for consideration to the draft policy.

Submission	Name	Date	Public Comment
1	Ted Doolittle	April 27, 2021	The proposed policy does not require the HIA to give consumers a balanced view of the consequences of not opting out.  Need to add language such as the following: "the consent form must establish in clear, plain language that the consumer is aware of and understands the consequences of not opting out. The consent process should include specific common use cases for the data and must include required questions affirming that the consumer is aware of the main categories that the information will be used for."
2	Dr. Velandy Manohar	April 27, 2021	I was reviewing this vital and interesting document. One detail stood out. Despite being more or less informed about HIE and CONNIE, I have somehow missed who or what HIA {Health Information Alliance} is and how it intersects with CONNIE and OHS. { second Line of second paragraph} Who constitutes the HIA? To whom is HIA accountable to ? and what is the mechanism of



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			oversight? This is critical piece of information that we all need to be familiar with and understand how it fits into the development of Integrated Electronic Health Information Systems. [Second Sentence] Thank you very much.
3	Dr. Velandy Manohar	April 27, 2021	Another point for clarification. Peculiarly these pages under heading 17b-59d Statewide HIE, OHS Consumer Consent Policy. Recommendation are not numbered. Further on the last page- 3/3 the document suddenly ends. It is Not signed off with any anyone's imprimatur.
4	Howard Selinger	May 3, 2021	It's about time and I ENTIRELY agree with the "Opt-Out" provision as opposed to opt-in. Let's get moving!
5	Jennifer & Michael Truss	May 3, 2021	People should not have to "opt out" of this program. If someone wants to join the state's collection of personal information, let them ask to join. If a patient does not ask to join they should automatically NOT be uploaded into this system. Patients should not be required to "proactively" ask to opt out. Thank you.
6	Renee Broadbent	May 5, 2021	*Please refer to PDF attachment on behalf of SOHO Health*
7	Ellen Andrews	May 20, 2021	*Please refer to the PDF attachment in email*  Please find attached public comment on OHS's privacy plan for the HIE. Included is a copy of the sign on letter from advocates to OHS on the same subject in March 2020. If you have any questions, let me know. Thank you
8	Susan Israel	May 24, 2021	*please refer to PDF attachment*



9	Judy Omphroy	May 25, 2021	<p>Hello Tina,</p> <p>Here are a few comments re: the draft policy.</p> <p>I would like the policy to include the variety of communication vehicles that will be used to insure that all residents will be informed of the policy and their rights and options.</p> <p>Additionally, frequency of Communications such as : reminders to make updates, Changes and updates to policies and procedures, etc.</p> <p>Section 5 discusses Use Cases, how will these be communicated to consumers?. How will updates be communicated? It sounds like it will be up to the consumer to check a website periodically. ( not realistic). It might be helpful if an explanation of a use case is included. My assumption is that this is where it is explained who will have access to a person's data and how. (It will be hard to opt in if I don't know who is accessing my information. )</p> <p>If there is going to be a place where someone can see who accessed their data, that would be helpful to include.</p> <p>Describe who will be monitoring adherence to policy? Frequency? How?</p> <p>What precautions are being taken for privacy and security. If they are pursuant to the specific statutes stated in the introduction, links to those statutes should be included.</p> <p>Please note that I only read through the policy once and very quickly so if I stated things that are already there , I apologize. Just wanted to meet the deadline and this is the only time I have to look at it.</p>
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10	John Brady	May 25, 2021	*Please refer to PDF attachment on behalf of CT Hospital Association*
11	SB Chatterjee	May 25, 2021	*Please refer to PDF attachment*

### Consumer Consent Comments Open Questions

All of the commenters made excellent suggestions and insights about the draft and consent policy, many of which have been incorporated into these revised draft recommendations. However, some raise important questions about the detailed operations of and the planned or potential applications of data in the HIE. Given the early stage of onboarding operations that HIA is currently developing and, where possible, operationalizing all possible and permissible applications at this time is not feasible. The table below summarizes many of the key themes represented by the public comments received that were not included in the revised draft, for the reasons stated above, but that require additional clarification and continuous development and improvement of this policy.

Topic	Open Issues
HIE Compliance	Which body has oversight over the HIA? The HIA is governed by a Board of Directors with State representation, including the State Health Information Technology Officer as the Chair, tasked with adherence to statute and its contractual obligations to the State.
Commercial Uses of Data	HIA will not sell any patient data within the HIE for any commercial purpose. All disclosures of patient PHI will be consistent with applicable state and federal law and HIA policies.
HIA status as a non-State entity	Some commenters agree with the design of the HIE as a non-State entity to promote it as a neutral, trusted entity.
How will informed consent be obtained?	Reflected in the policy, but also is an existing legal and professional obligation.



<p>How will patients be validated?</p>	<p>HIA is working with its tech partner and has convened a Patient Access Taskforce to develop a policy around how to meet patient validation and access requirements of 21<sup>st</sup> Century Cures Act. Part of that will be to develop recommendations and policy around patient validation. These recommendations are anticipated to be provided to the HIA Board of Directors at its September 2021 meeting for a first read, and tentative approval at the October 2021 meeting.</p>
<p>Emphasis on the importance of inclusion of race, ethnicity and language data</p>	<p>The revised policy includes a requirement that this policy account for Culturally and Linguistically Appropriate Standards.</p>

**Connecticut Five-Year Statewide Health Information Technology Plan  
Draft Environmental Scan Report**

In addition to OHS’ consumer engagement activities regarding the HIE patient consent policy, pursuant to Conn. Gen. Stat. § 17b-59a(c), we are also tasked with the development of a state-wide health information technology plan (Plan) in consultation with DSS and the HITAC to “establish electronic data standards to facilitate the development of integrated electronic health information systems for use by health care providers and institutions that receive state funding.” This Plan further requires that we review and, as indicated, periodically revise it.

OHS is currently drafting recommendations for revisions to the Plan as the State’s HIE is now operational and will continue to expand its capabilities. Consistent with OHS’ responsibilities for these HIT efforts, a draft updated HIT Environmental Scan Report was presented to the HITAC on June 17, 2021. This draft, while focused more broadly on the State’s overall HIT infrastructure, many of the findings are of specific importance to OHS’ patient consent policy recommendations. For this report, over 1,200 stakeholders including representatives from hospitals and health systems, community-based organizations, health plans and payers, State



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agencies, behavioral health providers and consumers, were engaged for input about this effort. From the input received, OHS has identified several themes of importance to the development of the HIE patient consent policy. These include:

- Strengthening and sustaining Connie;
- Fostering systems to support the social determinants of health needs of Connecticut residents;
- Enabling better coordination and data integration among state agencies
- Fostering electronic health records (EHR) adoption;
- A best possible medication history HIE service, connected through Connie; and
- Strengthening privacy of health information for patients and families.

However, one common theme throughout most of the stakeholders’ feedback emphasized the crucial importance of effective, robust, and easily understandable outreach and stakeholder engagement to promote a high degree of understanding of the complex HIT landscape in the state and the benefits of the HIE.

**HIT Plan Recommendations Emerging Themes**

Many of the key findings are already included in the draft Patient Consent Policy recommendations, but several commenters also raised important issues for further review and consideration as the State’s HIT initiatives continue to develop and mature.

Theme	Comments
Patient privacy and consent	The importance of meaningful and effective consumer understanding of their rights and impact of consent decisions is fundamental to the effective development of the Consent Policy.
Consumer education and outreach about the HIE	One theme addressed the need for a robust consumer engagement plan, addressed in Section 4 of OHS’ Patient Consent Policy recommendations. Indeed, many stakeholders lacked a comprehensive understanding of the HIE and, for many health providers, even certainty whether they





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	participated in an HIE at all.
Provider education and outreach about the HIE	These findings also identified a lacked of a comprehensive understanding of the HIE and, for many health providers, even certainty whether they participated in an HIE at all. As front line providers, it is highly likely that patients will seek information from these stakeholder, making their accurate understanding of the HIE crucial for patients.
More robust data analytic capabilities	Many commenters noted the benefits of increased data analytic capabilities that may be implemented through the HIE in coordination with participating providers. This may include better inclusion of data concerning the social determinants of health and their impact of the health of our residents. However, these possible use cases must still a key aspect the consumer outreach plan consistent with the requirement for meaningful informed choice.
Community Health, Public Health, organizations	More complete integration of full spectrum of health data will also enhance trend identification and options for improvements in the health care system.

OHS remains committed to continuing our robust, transparent and collaborative efforts for the development of comprehensive and stakeholder-centric policies concerning these important elements, with emphasis on consumer education and ongoing engagement.