March 9, 2020

Allan Hackney
Health Information Technology Officer
Office of Health Strategy
450 Capitol Avenue, 1st Floor
Hartford, CT 06106

RE: Response of The Connecticut Hospital Association (CHA) to the February 19, 2020 notice issued by the Office of Health Strategy (OHS) seeking "Feedback on DRAFT Consent Design Guiding Principles"

Dear Mr. Hackney:

CHA respectfully submits the following comments addressing the December 2019 Final Report And Recommendations Of The Consent Policy Design Group of the Health IT Advisory Council (the "Final Report").

It is evident that the Consent Policy Design Group engaged in thoughtful and wide-ranging discussions to inform and create the draft Guiding Principles and recommendations in the Final Report. We are grateful to them for their efforts, and appreciate the hours of work and care the Design Group members, staff, and consultants dedicated to creating the work product.

CHA appreciates the opportunity to comment on the Final Report, and looks forward to working with OHS and the Health IT Advisory Council as they develop and finalize the consent process.

Our comments separately address each of the 19 recommendations set forth in the Final Report. We included the text of each recommendation below, in italics, for easy reference.

Recommendation 1

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

CHA comment: We support consumers receiving clear, uniform, practical choices for how their information may be shared through the statewide health information exchange (State HIE). We urge that the State HIE materials be particularly clear about information sharing choices; specifically, that such choices affect only data exchanged by and through the State HIE. Even if a patient opts out of the State HIE, data will continue to be exchanged *outside* of the State HIE process, for myriad permitted purposes. Unless this is very clear, there is substantial risk of confusing consumers.

Further, if the State HIE intends to collect and retain data apart from provider-to-provider or provider-to-patient uses, that intention should be made obvious to and understandable by patients, and should include a well-defined listing or description of the various uses the state will have for the data. While an underlying principle for the consent process is to follow HIPAA, patients should be advised that HIPAA rules often will no longer apply to data once in the hands of the state.

Many state agencies are neither HIPAA covered entities nor HIPAA business associates. DSS is a significant exception because DSS is a HIPAA covered entity as a healthcare payer program. Conversely, most state agencies have no HIPAA obligations controlling data use or data release, unless those obligations are created by Connecticut statute. While it makes sense to explain to patients that hospitals and other providers are permitted to provide the state with data pursuant to various HIPAA sharing rules, it would be misleading to infer that those data are necessarily HIPAA protected once they are in the state's control.

Consider that, with very few exceptions, a HIPAA business associate must take instruction from a covered entity as to any limitations on use of data received from the covered entity. A business associate must return or destroy data from a covered entity (with limited exceptions) when the covered entity instructs, or when the relationship ends. Data that are collected by the state are no longer subject to directives from the covered entity that sent the data. In addition, after the state collects the data, the state has no HIPAA obligation to: (1) stop using the data; (2) return or destroy the data; or (3) inform patients of continued uses of their data. A meaningful consent process should include detailed explanations of these differences when patient information becomes state collected data.

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.

CHA comment: All educational materials should be centrally and uniformly sourced by the state, including providing the expectations for how the materials are to be distributed.

Explaining that the HIE will advance the ability of providers to share data with each other and with patients is important, but even more essential is building trust with consumers and patients by being openly transparent about other uses, including how the state will use the data.

To ensure that consumers have a full and transparent understanding of why they are being asked to share their data with the State HIE, the state's role in the HIE should be fully explained, including that the state is mandating hospital and provider participation in the State HIE, and that the state (and others) will utilize consumer data for various projects and purposes.

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).

CHA comment: We support wide distribution of educational resources that are developed and approved by the state. For clarity, the Office of Health Strategy is not merely a partner of the HIA (as

inferred in Recommendation 3). By law, OHS retains administrative authority for the State HIE, which includes the HIA. OHS, not the HIA, should make decisions about the patient consent process, and educational materials describing consent for the State HIE, consistent with regulatory rule-making requirements and administrative procedures (as discussed in Recommendation 19).

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.

CHA comment: We agree that, before a use case goes into production, recognizing what patient and consumer consents may be needed is important. We strongly caution, however, that obtaining re-consent from patients and consumers for each new use case is infeasible. Other than at point of service, which does not occur frequently for most patients, obtaining written feedback or a patient's affirmative consent is difficult.

Additionally, patients should be informed that data that is incorporated into a provider's records or carrier's records will not be removed even if the patient opts out of continued participation in the State HIE.

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).

CHA comment: We disagree with this principle if, and to the extent, it is intended to require providers or carriers to amend their HIPAA Notice of Privacy Practices (NPP) to specifically identify the State HIE. Patient consent forms or educational materials, or notices if needed, created by the state, should provide that information. 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.

CHA comment: We support this principle. The State HIE should develop a uniform consent process with associated consent management tools that are user-friendly for providers and patients, and that do not require providers and carriers to create unnecessary steps or internal processes to capture consent or to document notice of HIE participation.

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.

CHA comment: We support this principle. We caution that 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.

CHA comment: For the mechanisms used for expressing consent, we support ease of use for providers, carriers, and patients. We caution that expectations for managing consents (including retention, linking to patient and consumer records, and security for digital versions) should be given careful consideration to ensure that State HIE participants are able to comply using existing systems and tools, and to avoid creating added costs 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.

CHA comment: We support clear messaging to patients and consumers about consent and revocation of consent. The recommendation for the State HIE is for an opt out process. 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). As stated above, it is critical to convey that a revocation (or opt out) of the State HIE does not affect other data sharing that is outside of the State HIE, or continued use of data by certain state agencies or providers that have integrated the data into their systems.

We urge 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 recent, media-covered episode of a family that professed significant confusion and disagreement (which eventually became the basis for a lawsuit against the state) about how, in that case, DPH collects, uses, and shares immunization data, provides a clear example of why communication about how the State HIE will collect, use, and share data should be comprehensive and transparent.

We also urge 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. Because the State HIE use cases are not yet known, it is not obvious whether some use cases might require a HIPAA-compliant authorization. A HIPAA-compliant authorization must utilize specific revocation language, per HIPAA rules.

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.

CHA comment: We have one comment and one question about recommendation 10.

Comment: We agree that vendors and contractors should be aware of, and agree to comply with, applicable consent policies set by the State HIE. This presupposes that all policies are consistent with state and federal law, including HIPAA. Pursuant to HIPAA regulations, the HIE is necessarily the business associate of the covered entities that supply PHI to the HIE. Those covered entities, by law, will not be the business associates of the HIA or the State HIE.

The State HIE is not a covered entity, but as a business associate, the HIE has an obligation to require vendors that may be exposed to PHI to be its (subcontractor) business associates, as part of the contracting process.

Question: 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.

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.

CHA comment: Hospitals are HIPAA covered entities, and their data are protected and handled consistent with HIPAA rules and regulations. Requiring safeguards that providers already must follow pursuant to federal law is redundant and does not increase privacy or security of the data.

Further, entities that participate in the State HIE that are not covered entities or business associates **cannot** be transformed into HIPAA entities by contract or state policy, but they can be asked to follow similar safeguards. It is critically important to HIPAA compliance for all participants to know which entities are required to follow HIPAA, and which are not. The rules for exchanging data between HIPAA covered entities differ (sometimes dramatically) from the rules for sharing outside of HIPAA regulated entities. The consent policies should reflect and explain each of these legally defined and regulated roles.

Similarly, the varied roles of the State HIE and the state should be clarified in consent policies and consent materials. As discussed above, many state agencies that likely will have access to data from the HIE are not bound by HIPAA pursuant to federal law.

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.

CHA comment: We urge careful consideration of consent and authorization issues presented by specially protected and sensitive data. Which data can be exchanged through passive consent (opt out or through a notice) is significantly distinct from fact patterns (or use cases) that would require a HIPAA-compliant authorization pursuant to 45 CFR 164.508, or additional, specific written consent pursuant to 42 CFR part 2 (the federal rules that control substance use disorder confidentiality).

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.

CHA comment: We support this concept, and agree that the State HIE must follow all mandated federal interoperability standards. But we caution 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.

CHA comment: We support this concept but caution 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.

CHA comment: We support having a complaint process for consumers,but that process must recognize that covered entities cannot delegate or avoid their federal obligations under the HIPAA breach notification rules set forth in 45 CFR 164.400-414. Any process concerning a complaint that may relate to breach or the need to conduct a breach investigation must be fully aligned with those federal rules. Additionally, hospitals have an obligation, pursuant to the Medicare Conditions of Participation, to evaluate and respond to all patient complaints. The State HIE should be required to inform hospitals as soon as possible about any patient complaint involving a hospital participant.

Recommendation 16

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

CHA comment: We support this principle. We caution 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.

CHA comment: We support this principle. While not discriminatory, 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.

Recommendation 18

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

CHA comment: We support this principle. We urge that assessments be designed in a way that creates little or no burden for providers and patients.

Consistent with our earlier comments, we caution 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 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.

CHA comment: We have comments and two questions about Recommendation 19.

Comments. Pursuant to Section 17b-59e(b) of the Connecticut General Statutes, hospitals and laboratories are mandated to *participate* in the State HIE, as follows:

> Not later than one year after commencement of the operation of the State-wide Health Information Exchange, each hospital licensed under chapter 368v and clinical laboratory licensed under section 19a-30 shall maintain an electronic health record system capable of connecting to and participating in the State-wide Health Information Exchange and shall apply to begin the process of connecting to, and participating in, the State-wide Health Information Exchange.

The steps that a hospital or lab must meet to be compliant with the mandatory participation clause in Section 17b-59e are still unknown. We also do not know which data will be required to be sent to the

State HIE in connection with the statutory mandate to participate. Importantly, a state law mandate to participate in the State HIE is not sufficient under HIPAA to also mandate sharing of protected data.

Hospitals and labs are not allowed to delegate their HIPAA compliance obligations to the State HIE. However, HIPAA recognizes that a state may expressly mandate reporting or disclosure of protected health information under the "required by law" rule discussed in 45 CFR 164.512.

To the extent that the state, or the State HIE, intends to require by law certain data be disclosed by hospitals and labs (and other providers) to or through the State HIE, the detailed requirements of 45 CFR 164.512 would need to be met.

Consistent with the consent principles, and state law governing the operation of the State HIE, required-by-law data collection mandates should be clearly explained in patient education materials, consent policies, and forms. Otherwise, patients will not have a full or fair picture of their rights, or options, regarding consent for sharing their data with the State HIE.

Questions relating to Recommendation 19:

Question 1: 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?

Question 2: To what extent are actions and decisions of HIA subject to due process and administrative procedures applicable to state agencies?

Sincerely,

John J. Brady III
Senior Vice President, Strategic Planning and Organizational Performance/CFO

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