CONNECTICUT HOSPITAL ASSOCIATION

April 24, 2020

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

Dear Mr. Hackney:

The following are the Connecticut Hospital Association's comments concerning the proposed Qualified Data Sharing Organization Agreement (QDSOA) labeled "QDSOA Version 8.5 09-20-2019" consisting of 57 PDF pages. This version 8.5 was the only draft (and format) of the QDSOA provided to the Connecticut Hospital Association ("CHA") for review.

We recognize that some hospitals (and other stakeholders) have been invited to provide feedback on the proposed QDSOA. We note, however, that not all Connecticut hospitals have been invited to provide feedback on, or are even aware of, the materials that they will be asked to sign. Given the urgency of the COVID-19 response in Connecticut, all hospitals should be given reasonable time for their in-house legal teams, or outside counsel, to review and provide feedback on the proposed materials.

Context and Preliminary Issues

The draft QDSOA is not tailored for Connecticut's Health Information Exchange (HIE) planning or process. It is, to a large degree, a cut and paste of the Michigan MiHin system materials. While we acknowledge that there can be efficiencies gained by using another state's or another entity's existing materials, that can only be justified when care is taken to align the materials with Connecticut's process, laws, goals, and objectives. The undertaking needs to be thoughtfully considered and properly aligned, from the start.

We do not believe that these materials are the right starting place, and we repeat our request that OHS utilize a more flexible, and manageable framework. Absent any indication from OHS that it will use another, more suitable framework, we are now compelled to address the multitude of concerns and questions that are raised if Connecticut hospitals are forced to use some version of these draft materials.

Here is an overview of our chief concerns (a walk-through of specific concerns follows the list of chief concerns):

1. **Draft QDSOA Documents Are Not Based on Connecticut HIE Goals and Laws.** Failing to use Connecticut's goals and HIE planning as a framework and, instead, substituting Michigan's framework fails to capture the obligation set forth in Connecticut General Statutes Section 17b-59d(c) that: "All contracts or agreements entered into by or on behalf of the state relating to health information technology or the exchange of health information shall be consistent with the goals articulated in subsection (b) of this section and shall utilize contractors, vendors and other partners with a demonstrated commitment to such goals."

Pursuant to 17b-59g, the HIA is working on behalf of the state, and is subject to the "powers, purposes and restrictions of 17b-59a, 17b-59d, and 17b-59f" when performing "the acts and things necessary and convenient to carry out the purposes of [17b-59g] and section 19a-754a."

The materials should align with Connecticut's HIE planning process, Connecticut laws, Connecticut IT assets, and Connecticut's consumers. Using the pre-made Michigan framework does not achieve this.

2. **Statutory Participation Mandate Does Not Relieve Obligation To Create Documents Which All Stakeholders May Modify.** Pursuant to Section 17b-59e of the Connecticut General Statutes, hospitals and laboratories are subject to the following mandate: "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."

Hospitals (and labs) have no choice but to engage with the State-wide Health Information Exchange, but that should not mean that they are required to agree to whatever contract is presented by the Health Information Alliance (HIA) or OHS. If that is the case, it defeats the purpose of a contract; it also relegates the contract to a sovereign fiat, to be imposed without due process protections, adherence to administrative procedures, or the implied condition of good faith and fair dealing that should underlie every contract in Connecticut.

A hospital's or lab's only current path to compliance with the statutory mandate of Section 17b-59e is to enter into either the Qualified Data Sharing Organization Agreement (QDSOA) – the draft for which is the main subject of this communication – or the Simple Data Sharing Organization Agreement or SDSOA. (To date, the SDSOA has not been subject to reasonable vetting.) Both the proposed QDSOA and proposed SDSOA are copied in large part from the Michigan MiHin HIE system, and were not designed to reflect Connecticut's needs or HIE planning. **We urge OHS to add other, more feasible and reasonable options for compliance with Section 17b-59e that serve the goals set forth in Section 17b-59d.** At a minimum, to allow an informed choice, if the QDSOA or the SDSOA are the only available options, both sets of materials should be contemporaneously vetted, revised, and refined before parties are made to consider which option to sign.

3. **Patient Consent and Transparency.** The HIE Entity, and OHS, should be fully transparent within the QDSOA materials with respect to: the scope of data intended to be collected; the scope of uses for the data; how patient consent is obtained; and whether the HIA, OHS, or some other entity or organization makes those decisions. There is a lack of transparency, which makes it difficult to near impossible for stakeholders to make an informed choice about how to engage with the HIE. If this were a fully voluntary process, that might be an acceptable approach. But for hospitals and labs, where the process is not voluntary, it is not acceptable.

4. **Clarification of Participation Requirements.** Better clarity is needed on what hospitals and labs (i.e., mandated participants) are required to do to meet the participation clause of Section 17b-59e. Also essential to this endeavor is clarifying whether OHS or the HIA decides what data are *required* to be shared and who has access to those data. The proposed QDSOA does not address this critical component, and it is not apparent in any other proposed materials.

5. **Sale of Patient Health Data.** The proposed materials are also vague about what data or services will be available for sale through the HIA or any future part of the State-wide Health Information Exchange. The QDSOA documents indicate that there will be sales of services or data through the HIA, but it is not

evident what that means. Such ambiguity raises a substantial concern that selling services or data through the HIA may not be consistent with Connecticut or federal laws.

Issues Raised During April 9th Legal Workshop Call

Several legal representatives and other identified stakeholders were invited by the HITO to a group call to discuss the QDSOA. The call was held on April 9, 2020, and had a pre-set agenda that covered some issues, but in no way addressed all of the concerns or problems with the proposed QDSOA raised by stakeholders.
For the items that were covered on the call, there was near universal agreement among the call participants that several portions of the QDOSA require substantial revision. As a result of that call, we anticipate that the HITO and/or the consultants will present revisions to the discussed areas along the following lines:

- **Liability/Insurance**: The insurance ceiling should be aligned with available insurance, not the arbitrary $500k cap in the draft QDSOA, and indemnity clauses should be more reciprocal;
- **Governance**: Any clause that forces an organization to delegate its authority to the will of the HIA, or take any action not aligned with its own core policies, is not acceptable;
- **Dispute Resolution**: Binding arbitration is not acceptable as a form of dispute resolution;
- **System Integrity and Availability**: Security requirements should be reasonable; the audit provisions are unacceptable; the QDSOA and HIE framework must incorporate 21st Century Cures Act regulations (e.g., interoperability, information blocking, patient access); downtime notice should be a lighter footprint and a centralized process;
- **Consent**: It should be made clear in the QDSOA that the OHS consent process plays a significant, perhaps controlling, role in the HIE operations. While the details may need to be worked through by OHS process, those controls and the recognition of patient rights must be linked back to the HIA materials.

Since these issues are already under revision, and it is anticipated that there will be further opportunity for stakeholders to react to a next draft, our detailed feedback does not focus on these areas.

Detailed Feedback On The Draft QDSOA

Below we have provided a walk-through of specific concerns and questions raised by the draft QDSOA. These are in addition to the issues outlined above.

The page numbers used in the feedback below correspond to a PDF version of the proposed HIA QDSOA labeled "QDSOA Version 8.5 09-20-2019" consisting of 57 pages. This was the only draft (and format) provided to CHA for review.

[**Page 1**]
In the very first recital, Health Information Alliance, Inc. is abbreviated as "HIE Entity". But "Entity" is used throughout. Perhaps it should be **"Entity" or "HIE Entity"** in the recital.

In 1.1 Definitions. The Definition of "Applicable Laws and Standards" includes a specific reference to the **Connecticut Health Information Technology Commission**. No such body exists in Connecticut. There is, however, a Michigan Health Information Commission, in Michigan. The QDSOA materials should be focused on Connecticut's HIE planning, and not Michigan's separate, distinct, and voluntary, system.

- Question: To what degree is the QDSOA a copy and paste of Michigan's system? What efforts were made to have the Connecticut HIA materials reflect Connecticut law and/or HITAC planning for Connecticut?

If terms are necessary for the QDSOA, they should be meaningful citations to relevant Connecticut laws and regulations, where applicable.

[**Page 2**]
"Entity Board" is defined as "the organized body as defined by Entity's bylaws that oversees the Entity Services. Unless otherwise noted, all references to Entity Board shall be deemed to include its designee."

> Question: What is the relationship and/or distinction, between the Entity Board and the State-wide Health Information Exchange as set forth in Sections 17b-59d and 17b-59g of the Connecticut General Statutes?
>
> Question: Is the Entity the sole way that the State-wide HIE will function?

[**Page 3**]
Definitions. "Service Levels" is defined as having the same meaning as "ascribed to it in the **'Limited Warranty'** Section of this Agreement." The proposed Agreement does not have a "Limited Warranty" section.

[**Page 4**]
2.1. If there is no meaningful distinction between the terms "Use Case" and "artifactual Use Case" the word artifactual should be removed (each time it appears in the QDSOA) to reduce confusion. If there is a distinction, it should be plainly explained.

[**Pages 4-5**]
3.2. The materials state: "In the event PO provides access to Consumer Users, PO is responsible for allowing access only as indicated by such Consumer User for any health information it sends, receives, finds or uses through Entity Services."

- Question: What does this restrict? How does this restriction differ from obligations under 45 CFR 164.524?

3.2. The materials indicate that the Parties shall comply with the HIPAA Addendum, Attachment E. Not every party to the QDSOA will be a HIPAA Covered Entity or Business Associate. HIPAA does not permit non-HIPAA entities to share PHI in the same manner as between HIPAA regulated entities, or as covered entities or business associates.

- Question: What rules will the non-HIPAA entities follow, given that the HIPAA Addendum is not appropriate for them?

[**Page 5**]
3.3. Patient Care. Only the last sentence of this paragraph is appropriate. It is legally incorrect to declare that, in all cases, a PO is "solely responsible" for decisions "taken or not taken" involving patient care, UM, QM. The last sentence, absolving the HIA of responsibility for actions of others is appropriate.

3.4. System Security. This section references compliance with the HIPAA Addendum (Attachment E). Not every party to the QDSOA is a HIPAA Covered Entity or Business Associate. HIPAA does not permit non-HIPAA entities to share PHI in the same manner as between HIPAA regulated entities.

- Question: What security rules and attachments will apply to non-HIPAA entities?

[**Page 6**]
3.5.2 Audit. This section is unworkable. On the April 9, 2020 legal call, there were multiple concerns raised with the audit section of the QDSOA. We await a reworked version based on the call.

3.6 Cooperation. A PO should not be required to disclose information or take any action that would conflict with its own policies or procedures when cooperating with the HIE or Entity Board.

To the extent that this section references Dispute Resolution: On the April 9, 2020 legal call, multiple concerns were raised concerning the Dispute Resolution sections of the QDSOA. We await a reworked version based on the call.

3.7 Development of Compliance with Entity Operating Policies and Procedures.
Please confirm that there are not policies and procedures at this time, and that parties signing the QDSOA are required to agree, in advance, to unformulated materials that do not yet exist.

A PO should not be required to follow any policy or procedure of the HIA that would conflict with its own policies or procedures.

- Question: Why is there a reference to "HITRUST" in this section? Is HITRUST expected to be a requirement of HIE participants?

[**Page 7**]
4.3 Maintenance of Agreements. This section references Qualified Data Sharing Organization agreements. Does that mean "this Agreement"? If not this QDSOA, to what agreement(s) does it refer?

[**Page 8**]
5.3 and 5.4. The disclaimer of warranties and details of 5.4 should be reciprocal for Participants.

5.5 Carrier lines. It's rare to see a statement like this about conduit or outside connectivity services. It's unclear why this is necessary. If it is necessary, then it would be appropriate to add: *Nothing herein alters Entity's obligation as a Business Associate to utilize secure transmission methods when sending PHI.*

[**Page 9**]
5.10 Usage of Message Content. This section requires the PO to represent and warrant that it will only use Message Content in accordance with the QDSOA and the HIE Entity's related documents. Somewhere, not necessarily here but this is a good place, there should be a clarifying statement that indicates: *Nothing herein shall affect PO's ability to utilize data created or received from a different source than through Entity Services, including data that are similar or identical data contained in Message Content.*

5.12 Agreements with Technology Partners. This section requires POs to direct partners to cooperate with the HIE Entity and other TDSOs. It is unlikely that prior PO vendor contracts will be specially adjusted for the HIA's needs. Does the QDSOA require revisions to a PO's existing and future vendor contracts?

[**Pages 9-10**]
Section 6 discusses payment and fees. Please explain when payment and fees are anticipated to occur. It is not evident what payment or fees would be due to, or paid to, Participants or the HIE Entity.

- Question: What services or data are intended to be sold through the HIE?
- Question: Will there be any services or data offered for sale to organizations or individuals that have not signed the QDSOA or the SDSOA?
- Question: What controls are in place to guard against violations of 45 CFR 164.502 (prohibition on the sale of PHI) or the regulations supporting the 21st Century Cures Act?

6.3 Taxes. What taxes are anticipated from Entity Services? This section indicates that the Party receiving the services is responsible for payment of taxes, but it is not clear which parties are responsible under state law for collecting taxes or paying DRS. The documents must detail which Connecticut taxes apply.

6.4 Third-party Fees and Charges.

- Question: What third-party fees, Connecticut taxes, or charges does the HIE Entity anticipate would apply?

[**Page 10**]
7.2 Equitable Relief. Please change the word "preliminary" to "temporary" in the phrase: "Consequently, the disclosing party shall be entitled to obtain preliminary and permanent injunctive relief to restrain such unauthorized disclosure or use…." While the wording is correct for Michigan law, and federal courts, Connecticut law uses the term "temporary" injunction, not preliminary. To be consistent with the definitions section on page 2, it would also be appropriate to change disclosing party to the defined term Disclosing Party.

If terms are necessary for the QDSOA, they should be meaningful citations to relevant Connecticut laws and regulations, where applicable.

7.3 Protected Health Information. This section indicates that the HIPAA Addendum applies to all Parties' use, access, and disclosure of PHI. Not every party to the QDSOA is a HIPAA Covered Entity or Business Associate. HIPAA does not permit non-HIPAA entities to be made into Covered Entities or Business Associates, or to share PHI in the same manner as between HIPAA regulated entities.

- Question: What rules will the non-HIPAA entities follow, given that the HIPAA Addendum is not appropriate for them?

[**Page 11**]
Section 8.2 Termination. This section sets forth the conditions under which a party may terminate the QDSOA.

- Question: Please explain what type of event is anticipated by 8.2(b), relating to regulatory bodies and material risks?
- Question: If a party is required by Connecticut law to participate in the HIE Entity acting as the state-wide health information exchange, how can it terminate the QDSOA and still be in compliance with Connecticut law? Would it be allowed (required) to rejoin through the SDSOA? If the HIE was the breaching party, would the other party be released from its obligations pursuant to Section 17b-59e?

[**Pages 11-12**]
Section 9. Indemnification. The indemnification clauses should be reciprocal, and should not favor the HIE Entity by limiting the HIE Entity's indemnification obligations only to IP issues and failure to keep documents in place.

9.3 The end of the paragraph needs punctuation.

[**Page 12**]
Section 10. Limitations on Liability. We anticipate a new draft of this section, based on the discussions on the April 9, 2020 legal community call.

[**Page 13**]
11.1 Statement of Work.

- Question: What work is contemplated to be paid for through Statements of Work?
- Question: Will there be any fee-based services offered to organizations or individuals that have not signed the QDSOA or the SDSOA?

- Question: What controls are in place to guard against violations of 45 CFR 164.502 (prohibition on the sale of PHI) or rules from the 21st Century Cures Act?

12. Use of Message Content.

- Question: If "Permitted Usage" is confined to the Use Case only, and that Use Case does not allow for Additional Permissible Use, does that effectively prohibit a PO from combining the Message Content into their EHR or record?
- Question: How would that be managed to remain in compliance with other requirements, including access rights (45 CFR 164.524) and any required by law requests (45 CFR 164.512)?

[**Page 14**]
Section 14 Use Cases.

14.1 This section indicates that the "Entity Board" has "full authority to adopt new Use Cases" and 14.2 indicates that a PO "shall determine, in its sole discretion, whether to enter a Use Case." These statements are inconsistent with information shared by the HITO in various meetings that hospitals (which are mandated to participate in the HIE Entity) will be required to share data in connection with certain Use Cases. Specifically, the HITAC has identified preferred Use Cases and the HITO has clarified that hospitals will be required to participate in certain use cases, including those that relate to building a provider directory and master patient index.

- Question: Is 14.2 correct that a PO has sole discretion to enter a Use Case, or will there be more specific mandates requiring participation in specific use cases?
- Question: What is the regulatory source or authority for mandated participation in a Use Case by hospitals or labs?

14.3 Is "HIN" meant to be HIE or HIE Entity? "HIN" or "MiHin" is used well over a dozen times in the QDSOA and its attachments. If terms are necessary for the QDSOA, they should reflect that this is a Connecticut HIE, where applicable.

15.3 PO Participants and HSPs. Please explain what discipline is expected of employees of PO Participants by the PO? This does not seem feasible (or legal).

[**Page 15**]
17.2. NO WARRANTIES. This section references a definition of "Accuracy of Message Content" but there is no definition for "Accuracy of Message Content" in the QDSOA. Does this reference 5.7? The other warranties in section 5 (5.8, 5.9, 5.10) seem to be voided by 17.2.

["Liability" is spelled incorrectly in the second line.]

Section 18 General.
18.1. Third Party Beneficiaries.

- Question: Specific to the "notwithstanding" clause, what types of third party beneficiaries are contemplated?

[**Page 16**]
18.5 Waiver. Although the section is entitled "waiver" this is not a typical waiver clause. Further, it is contextually incorrect. The section states that there are no restrictions "Except for the Sections entitled 'Disclaimer' and 'Dispute Resolution' of this Agreement …." This description is not accurate and creates intra-contractual confusion. There are other restrictions that apply (see, e.g., Section 5). There are also multiple

Sections called "Disclaimers." This should be revised to be a customary waiver clause (which is just the last sentence in 18.5).

If further clarification of restriction of remedies is necessary (which it is not), it should be stated in terms similar to "Except as expressly set forth in this Agreement or other writing between the Parties…."

18.9 Nonsolicitation. This clause is too broad and unnecessary.

[**Page 17**]
18.12 Insurance. Is the cyber insurance also meant to cover HIPAA type breaches, not just loss of Confidential Information as set forth in 18.12(c)? Confidential Information does not include PHI per the QDSOA, page 2.

18.13 Dispute Resolution. As discussed on the April 9th legal call, binding arbitration is not acceptable. The majority of the participants on the call indicated a best efforts or mediation approach would be acceptable. No one on the call supported binding arbitration. The choices for the QDSOA are not limited to binding arbitration or a lawsuit. Cooperative problem solving and internal escalation should be encouraged and outlined in the QDSOA. We anticipate a new draft of this section based on the discussions on the April 9, 2020 legal community call.

18.14 Order of Precedence. This clause indicates that in the event of an express conflict or inconsistency, an attachment is to be followed over the text in the body (the first 19 pages) of the QDSOA. **It is essential to avoid confusion or misalignment between the attachments and the text in the body of the QDSOA.**

[**Page 20**]
Attachment A – Master Use Case Agreement

4.2 Additional Permissible Uses.

- Question: If Permitted Usage is confined to the Use Case only, and that Use Case does not allow for Additional Permissible Use, does that effectively prohibit a PO from combining the Message Content into their EHR or record?
- Question: How would that be managed to remain in compliance with other requirements, including access rights (45 CFR 164.524) and any required by law requests (45 CFR 164.512)?

[**Page 21**]
4.2.8. Enrichment. This section discusses that the HIE Entity may enrich data before sending.

- Question: Will the HIE Entity have a stored repository of data and/or PHI?
- Question: Which data will be stored and for how long?

[**Pages 22-26**]
Section 7, Section 8, Section 9: We defer to our hospital colleagues with frontline IT experience, and other stakeholders, to give feedback on these sections.

[**Page 27**]
Attachment B - Definitions
#2 Active Care Relationship. This section seems jumbled and needs more clarity.
Questions:

- Does the 24-month look back in #2.1 only apply to health providers who are responsible for managing the care of a patient?

- In #2.1, what does this clause mean: "unless notice of termination of that relationship has been provided to OHS?"
- Will OHS be tracking patient-provider relationships? If yes, under what authority?
- What is the lookback for payers and programs for #2.2?
- What does "asserted by a consumer" mean in #2.4? What is the lookback (if not 24 months)?
- What is the lookback for #2.5, OHS eCQMs?
- Where does a hospital encounter fit in this list for an active care relationship? What is the lookback (if not 24 months)?
- Where does a lab draw or patient encounter fit in this list? What is the lookback period (if not 24 months)?

[**Page 28**]
#11. Agency. This section defines "Agency" as the Office of Health Strategy. That is confusing as a number of state agencies may have a role in the HIE or with data change. Also, "Agency" does not appear to be used again in the QDSOA. Further, it is unsure what role OHS has that it needs to be the defined "Agency" for the HIE. Perhaps it would be best just to call it OHS.

[**Page 29**]
#19 Care Map.

- Question: Is it correct that the Care Map referenced in #19 will always be a "visual representation" in all cases? Will there be any narrative care maps that are not exclusively "visual"?

#23. Comprehensive Primary Care Plus (CPC+). This is a defined term in Attachment B that is not used elsewhere in the QDSOA. Similar examples: #31 Dashboard, #35 Data Lake, #78 Immunization Information System.

- Question: What is the intention for future use of these terms that do not appear in the QDSOA?

[**Page 30**]
#24. Confidential Information. This contains a different definition than the one contained in the body of the QDSOA at page 2. Based on QDSOA 18.14, this clause in Attachment B would control. Like or identical defined terms should be defined only once, unless there is a clear and specific reason to do otherwise.

#30. Critical Access Hospitals (CAH). Is the HIE Entity intending to exchange data with CAHs? Connecticut does not have any CAHs. (Michigan has approximately 37 CAHs.) Also, the "EHR Incentive Program" was revised in 2018 to be Promoting Interoperability.

[**Page 31**]
#37. Data Use Agreement (DUA).

- Question: Does the HIE Entity intend to utilize HIPAA defined limited data sets? If so, a HIPAA compliant DUA that meets the HIPAA rules would be needed. This definition would be inadequate.

#38. De-Identified. This definition is incomplete in that it references only 45 CFR 164.514(b)(2). Per HIPAA, de-identification can also be achieved by expert method as set forth in 45 CFR 164.514(b)(1).

- Question: Has the legal option pursuant to 45 CFR 164.514(b)(1) been intentionally left out of the QDSOA materials? If yes, why? That will make de-identification extremely difficult in many instances.

#40. Durable Power of Attorney for Healthcare. Connecticut law expressly does *not* utilize this mechanism for advance directives for care decisions. See Conn. Gen. Stat. § 1-350b; and more generally §§ 1-350 to 1-353,

inclusive, for more information. Connecticut *does* allow a POA for record access. See Conn. Gen. Stat. § 1-350h. This definition should be changed to be consistent with Connecticut law.
If terms are necessary for the QDSOA, they should be meaningful citations to relevant Connecticut laws and regulations, where applicable.

#41. eHealth Exchange – reads "see definition for Sequoia Project." Sequoia Project is also referenced at #88 and #122.

- Question: What role does the Sequoia Project have in the Connecticut HIE?

[**Page 32**]
#46 ands #47, referencing the "EHR Incentive Programs" should be revised to reflect the federal law changes made in 2018 to Promoting Interoperability.

#50. Facility/Hospital is a combined definition that only includes being a hospital. There should be a separate reference for facilities that are not hospitals.

[**Pages 32-33**]
#51 and #56 repeat a definition for FHIR, but not quite identically. There should not be two entries for FHIR.

[**Pages 33-34**]
#61 Health Information. This definition is odd. It is not the HIPAA definition, or from Connecticut law. What is its purpose?

#62, #63, and #64: These sections discuss OHS, the state-wide HIE law, and the HITO, including reciting portions, but not the entire text, of Connecticut's HIE statutes.

- Question: Is the HIA required to serve the goals as stated in #62 [17b-59d]?
- Question: What specific authority will HIA be given to act on behalf of OHS or the state [17b-59g]?
- Question: When HIA is acting on behalf of OHS or the state, what regulatory due process is required, or assured?
- Question: What powers, oversight, or responsibilities do OHS or the HITO with respect to the HIA?

[**Page 34**]
#69. Health Provider. This definition seems very loose and confusing. The definition should be made clear, and tied to Connecticut state law definitions.

#70. Health Provider Directory. This describes a provider directory as "the statewide shared service established by Entity…."

- Question: Does the HPD exist now or is it still to be built?
- Question: Will the HPD contain all providers in Connecticut, or only some providers in Connecticut?
- Question: Will out of state providers be included?
- Question: Who will own this directory, the Entity or the state, or other?
- Question: Will only entities that sign the QDSOA or SDSOA be eligible to use the directory as a resource? If yes, does that comply with both state and federal law, including Sections 17b-59d, 19a-904c and d, and the federal rules made to carry out the 21st Century Cures Act?
- Question: what access will state agencies have to the provider directory?

[**Page 36**]

#94 Participant. This definition reads "Participant means an organization that has agreed to the terms of any form of data sharing agreement with OHS or its successors or assigns." This is inconsistent with PO Participant used throughout the QDSOA. It also does not make sense.

- Question: What entities are contemplated as signing agreements with *OHS* for data sharing as part of the HIA process?
- Question: What "successors or assigns" is OHS anticipated to have?

[**Page 37**]
#96 Patient Data. This definition seems too broad, and not tied to any applicable legal definitions. There are data in provider and carrier systems that are not traditionally thought to be "patient data" that would be routinely shared in an HIE. Examples include: peer review, quality data, financial data, and research data.

Further, the sub-definitions should track HIPAA and/or Connecticut law on businesses that store electronic information. See, e.g., Chapter 669 of the Connecticut General Statutes, and its definition of "personal information".

#101 Pharmacist/Other Qualified Professional. This definition does not make sense.

- Question: What does it mean to "administer a prescription?" A provider (usually not a pharmacist) might administer a drug to a patient. A prescription might be logged or recorded in a system, such as in an EMR or the PDMP. But no one, including pharmacists, will "administer" a prescription.

#102 Physician Payer Quality Collaborative (PPQC): This "Collaborative" does not appear to exist in Connecticut. What organization is this meant to reference? There is a Michigan Physician Payer Quality Collaborative. Note: (from Michigan's state medical society): "The PPQC is a physician-led activity, facilitated by MSMS and its partners on the Executive Council with technical support from Michigan Health Information Network Shared Services (MiHIN)." https://www.msms.org/Membership/Executive-Council-of-Physician-Organizations/Physician-Payer-Quality-Collaborative-MSMS.

If terms are necessary for the QDSOA, they should be meaningful citations to relevant Connecticut laws and regulations, where applicable.

#107. Prepaid Inpatient Health Plan. This section references 1915(c) waiver programs for specialty services paid for by Medicaid.

- Question: Is there a specific plan for PIHP data to be included in the HIE Entity's activities?

[**Page 39**]
#123. Service Interruption. This should be cross referenced to Attachment G to avoid confusion.

#129. Specially Protected Information. This section references HIPAA, 42 CFR part 2 (both federal protections). It also expressly references "the state mental health code"; Connecticut, however, does not have a state mental health code. (Michigan has a mental health code.)
If terms are necessary for the QDSOA, they should be meaningful citations to relevant Connecticut laws and regulations, where applicable.

[**Page 40**]
#139. UConn Aims (also referenced in #28, #31). This section states that UConn Aims is party to a Memorandum of Understanding with OHS "to develop health data architecture to fulfill the obligations of OHS and this Agreement."

- Question: What role is UConn Aims expected to play in the HIA process?
- Question: Which OHS obligations is UConn Aims expected to fulfill?

#140. View Download Transmit (VDT). This describes VDT as a meaningful use objective.

- Question: Is the HIE Entity expected to enable consumers to access information through the HIE in a manner that would fulfill VDT objectives for promoting interoperability? If yes, by what year?
- Question: Should there be a more up-to-date reference to patient access rights and/or API obligations of the HIE in light of the regulations supporting the 21st Century Cures Act, including the Interoperability and Patient Access final rule, or other relevant federal rules or laws?

[**Page 42**]
Attachment C – Master Statement of Work.

- Please explain what types of data or services are expected to be sold through the HIE Entity?
- Question: Have those expectations been assessed for compliance with 45 CFR 164. 502 (prohibition on the sale of PHI), patient access rights under 45 CFR 164.524, and other federal rules including regulations supporting the 21st Century Cures Act?

[**Page 45**]
Attachment D -- Use Case Exhibit Template

This Attachment is blank.

- Question: Will there be an illustrative Use Case example in the final document?

[**Pages 46-54**]
Attachment E – HIPAA Addendum
The HIE Entity is required by federal law (HIPAA) to enter into a BAA with the Covered Entities that share data with the HIE. The need for a BAA is not (as indicated on page 46) "in consideration of the Entity's use of PHI from the CEs," it's because of the federal mandate. This factor is important for a variety of reasons, including that the HIE Entity must – at all times when handling PHI – follow the rules for HIPAA Business Associates. HIPAA non-entities cannot be made into HIPAA regulated entities by contract (BAA or otherwise).

The BAA should be informed by input from the Covered Entities that will be sharing data. The BAA should provide clarity on financial responsibilities for a breach by the HIE Entity.

This BAA could be modified to more closely track the HHS/OCR Sample BAA (including removing the myriad unnecessary and confusing references to HITECH). That approach will reduce confusion, provide CEs that engage with the HIE a comfort level that all requirements are being met, and ensure that no party is unfairly advantaged or disadvantaged by the terms of the BAA. It would also make sense to add provisions outlining how limited data sets can be used, along with corresponding HIPAA-compliant DUA terms in the BAA. Responsibility for notifying individuals and OCR in the event of a HIPAA breach should be controlled and determined by the involved CEs. The HIE Entity, as a business associate, should not be making those notification decisions unilaterally.

Additionally, not every entity involved in data exchange, or data access, through the HIE Entity will be a HIPAA entity (Covered Entity or Business Associate). Non-HIPAA entities should not be parties to a BAA.

- Question: what data sharing controls will be put in place for entities for which a BAA is not appropriate?

[**Page 56**]
Attachment G – Service Interruptions.
Reporting service interruptions should be easy, lightweight, and centralized. The process in Attachment G seems cumbersome.

The term “HIN” is used repeatedly in this Attachment G. The term “MiHin” is used twice. These appear to be terms directly from Michigan-MiHin materials, and not relevant to Connecticut.

- Question: Are the terms HIN and MiHin meant to be referenced in the Connecticut QDSOA materials?
- Question: What entity or vendor is expected to be responsible for the role outlined for the HIN in Attachment G?
- Question: What role, if any, does MiHin play a role in the Connecticut HIE?

Regards,

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JJB:ljs
By E-mail