



Strategic  
Health  
Information  
Exchange  
Collaborative

June 17, 2019

Don Rucker, M.D.

National Coordinator for Health Information Technology

U.S. Department of Health and Human Resources

330 C St SW, Floor 7

Washington, DC 20201

**Re: *Trusted Exchange Framework Common Agreement: Draft 2***

Dear Dr. Rucker:

On behalf of the [Strategic Health Information Exchange Collaborative](#) (SHIEC), which represents more than 70 health information exchanges (HIEs) across the nation, we appreciate this opportunity to comment on the Office of the National Coordinator for Health Information Technology's (ONC) second draft of the Trusted Exchange Framework and Common Agreement (TEFCA Draft 2).

As the unbiased data trustees in their communities, SHIEC member HIEs serve more than 75% of the United States population and are critical partners to advancing effective, efficient healthcare delivery locally, regionally and nationally. SHIEC HIEs have been committed to interoperability and have helped develop and deliver innovative solutions in their communities and states. As ONC works to finalize TEFCA, SHIEC will serve as a partner and a resource for ONC, particularly as the ONC's efforts to scale health information exchange nationwide are aligned with SHIEC's mission and purpose.



Strategic  
Health  
Information  
Exchange  
Collaborative

To that end, please see below the highlights of SHIEC's comments regarding Draft 2 of the TEFCA in addition to the attached detailed summary of thoughts and recommendations for your consideration:

- The importance of engaging various stakeholders (including SHIEC and others) early in the process of developing requirements and standards to ensure decisions can be operationalized;
- The impact of the proposed Information Blocking Rule as it relates to TEFCA, including whether entering into the Common Agreement (which expressly limits exchange purposes) may constitute information blocking; and
- The fundamental need for robust patient matching – that could be achieved through a centralized master patient index (MPI). SHIEC supports various forms of querying for a patient (including broadcast and targeted queries), but strongly believes that ONC must set measurable, common matching standards (e.g. thresholds for accuracy) to ensure nationwide interoperability. With substantial matching experience nationally, SHIEC welcomes the opportunity to engage further with ONC to establish workable national standards.

Thank you again for this opportunity to share feedback from the SHIEC HIE community. If you have any questions, please feel free to contact SHIEC's Kelly Thompson at [kelly.thompson@strategichie.com](mailto:kelly.thompson@strategichie.com) or 970-852-2166.

Sincerely,

A handwritten signature in black ink that reads 'Kelly Hoover Thompson'.

Kelly Hoover Thompson, CEO



**S**trategic  
**H**health  
**I**nformation  
**E**xchange  
**C**ollaborative

## Detailed Comments

### **I. TRUSTED EXCHANGE FRAMEWORK**

#### **A. Recognized Coordinating Entity (RCE)**

SHIEC agrees that the RCE should be a not-for-profit, neutral entity that is broadly trusted, transparent, free of conflicts of interest, and can ensure a level playing field for all stakeholders. SHIEC wants to highlight the potential difficulty of identifying an organization with ties to healthcare and technology that is entirely free of all actual or perceived conflicts of interest. To that end, SHIEC requests that ONC consider whether changes to the proposed framework may be appropriate.

Specifically, SHIEC recommends that ONC consider creating a steering committee (composed of federal partners and private industry leaders, such as HIEs/health information networks (HIN), hospital systems and state Medicaid agencies) to provide input and guidance on the development of the Minimum Required Terms and Conditions (MRTCs) and Additional Required Terms and Conditions (ARTCs). This committee will also ensure that governance and other decisions by the RCE are in line with the needs of local, state, and tribal communities nationwide. Additionally, a technical subgroup should be required for the development of the QHIN technical framework. As a collaboration of local HIEs across the country, with experience sharing data in a complex state and federal regulatory environment, SHIEC welcomes the opportunity to provide guidance to ONC as a participant on a steering committee, or in any way that will improve nationwide interoperability.

Finally, SHIEC recommends that ONC continue to develop a framework that ensures that electronic health record (EHR) vendors comply with the interoperability standards that support the goals of TEFCA. Many of the requirements outlined in TEFCA will require cooperation from vendors. Therefore, SHIEC recommends that ONC continue to develop a regulatory framework that will ensure that vendors are able to produce and export data and



**S**trategic  
**H**health  
**I**nformation  
**E**xchange  
**C**ollaborative

content in such a way to make parties to the Common Agreement, and the framework, successful.

## **B. QHIN**

SHIEC supports the revisions to the definition of a Qualified Health Information Network (QHIN) in TEFCA Draft 2; however, SHIEC recommends adding more specific requirements around a QHIN's ability to conduct patient matching and person location. Specifically, SHIEC strongly believes that ONC must set measurable, common matching standards (e.g., thresholds for accuracy) to ensure nationwide interoperability. SHIEC stands ready to offer its expert guidance to ONC on the value of robust patient matching and person location capacity. In particular, SHIEC can share knowledge gained from the development of the Patient Centered Data Home (PCDH), which connects HIEs from across the country using ADT-fed MPIs.

Additionally, SHIEC supports a probationary "provisional QHIN" step in the QHIN application process. SHIEC also sees value in collaborating with a cohort to ensure readiness of the infrastructure. With this in mind, SHIEC asks ONC to further explain the requirements of provisional QHIN, specifically the application of the common agreement to a provisional QHIN.

SHIEC encourages ONC to further explain the anticipated timelines that will apply to the proposed Cohort Deadlines and Onboarding for Provisional QHINs. Will the 18-month deadline in MRTC § 2.2.6 also be applicable for Provisional QHINs to onboard Participants and Participant Members? Notably, the timeline required for Provisional QHINs to onboard Participants and Participant Members will vary considerably based on the number and organizational complexity of the Participants and Participant Members that are part of a given QHIN network. In some cases, eighteen months could be unrealistic for Provisional QHINs to modify and renegotiate contracts with existing participants, though the MRTCs appear to contemplate a rolling onboarding process after QHIN status has been certified.

Finally, will Provisional QHINs be permitted to exchange data with one another during the provisional period, provided required contracts are in place with Participants and Participant Members? If so, will a Provisional QHIN be permitted to charge reasonable, cost-based fees to Participants and Participant



**S**trategic  
**H**health  
**I**nformation  
**E**xchange  
**C**ollaborative

Members when it begins exchanging data provisionally? SHIEC encourages ONC to consider elimination the Provisional QHIN status and instead condition the QHIN application and approval process on implementation of the requirements of the Common Agreement?

### **C. Participants, Participant Members and Individual Users**

The classifications of Participants, Participant Members, and Individual Users are reasonable though SHIEC would appreciate clarification on the following:

- Is a vendor, who on receives electronic health information (EHI) from a HIN on behalf of a Participant Member in the HIN (e.g., as the Participant Member's Business Associate), required to also be a Participant Member in the HIN? Alternatively, may the vendor's client, who is already a Participant Member in the HIN, agree to be responsible for the vendor's conduct, similar to such a Participant Member's responsibilities for its authorized users?
- Will participation in a QHIN require a HIN to give an individual access even if HIN's business associate agreement with its Participants does not authorize direct access or expressly prohibits it?
- Can an entity be a Participant in more than one QHIN? SHIEC also requests greater clarity on the impact of an entity's decision to be a Participant Member in more than one Participant network (if the Participants are part of different QHINs). For example, if Hospital System A participates in Regional HIE B and another Regional HIE C, and if those regional HIEs become Participants of two different QHINs, can Hospital System A continue to be a Participant Member of both HIE B and HIE C? What is the advantage / disadvantage of such an arrangement for the Participant Member? More examples of QHINs would be helpful and further clarification around total number nationwide would be helpful.



**S**trategic  
**H**Health  
**I**nformation  
**E**xchange  
**C**ollaborative

## **II. COMMON AGREEMENT & MINIMUM REQUIRED TERMS AND CONDITIONS**

### **A. Exchange Modalities**

SHIEC is comfortable with the proposed, required exchange modalities for QHINs and with the proposed definitions of QHIN Targeted Query, QHIN Broadcast Query, and QHIN Message Delivery. However, SHIEC believes that requiring QHINs to support QHIN Broadcast Query (as currently defined) is premature and will likely exclude various networks that already effectively share data from becoming a QHIN. Like the previously proposed Population-Level Data Exchange modality, QHIN Broadcast Query at a national level is not widely used or supported. Requiring QHIN Broadcast Query at this time will have the unintended consequence of unnecessarily (and too narrowly) limiting the number of organizations that can serve as QHINs. To encourage greater participation in TEFCA at the QHIN level, SHIEC proposes making the QHIN Broadcast Query optional.

Furthermore, SHIEC questions the viability of a QHIN Broadcast Query to meet nationwide-interoperability needs. Specifically, SHIEC posits that such a mechanism may not be as effective at matching patients as a centralized MPI, for example, and further could create significant resource strain on QHINs and others responding to massive quantities of such queries. Instead, SHIEC recommends that ONC consider whether a QHIN should be required to maintain a centralized MPI (or other algorithmic matching mechanism), which has already proven to be effective in existing national networks (e.g., PCDH). With its experience in the field, SHIEC would gladly provide any additional assistance to ONC in developing an appropriate matching framework.

Additionally, SHIEC supports the removal of the Population Level Data Exchange Modality included in TEF Part B and agrees that the data exchange ecosystem is not yet prepared to exchange in this fashion today. For the reason, and those listed above, SHIEC requests that language be added to § 7 of the MRTCs to clarify that Participants in a QHIN are not required to support all these modalities. For example, the mandatory language in §§ 7.1 and 8.1 should be revised to state that a Participant or Participant Member, respectively, may respond to a request for EHI in connection with a QHIN Query.



**S**trategic  
**H**health  
**I**nformation  
**E**xchange  
**C**ollaborative

## **B. Exchange Purposes**

SHIEC supports allowing QHINs, Participants and Participant Members to exchange EHI to the fullest extent permitted under Applicable Law (though, as stated in its comments to the Information Blocking Rule SHIEC believes there is a category of Community Health Information Organizations<sup>1</sup> that should be able to set reasonable privacy constraints in line with local or state needs), and appreciates ONC ensuring that regulations around interoperability of EHI comport with the requirements of the MRTCs.

### **i. Payment**

SHIEC is particularly concerned about narrowing the required exchange purposes to only a subset of Payment (Utilization Review), and sees this as a missed opportunity. Payers (both public and private) are increasingly relying on data exchange across systems, and SHIEC is confident that the use of the common agreement among payers will be critical to its success. SHIEC is concerned that removal of Payment as a required Exchange Purpose will dissuade many payers from participating in the Common Agreement, thereby diminishing the effectiveness of the Framework for patients. For this reason, SHIEC supports allowing QHINs, Participants and Participant Members to exchange EHI to the fullest extent permitted under Applicable Law.

### **ii. Business Planning and Development**

SHIEC also believes that further clarification is needed with respect to when EHI may be exchanged for Business Planning and Development—one of the remaining Health Care Operations Exchange Purposes. A Covered Entity (and its Business Associates), as those terms are defined by the Health Information Portability and Accountability Act and its implementing regulations (HIPAA), may disclose PHI to another Covered Entity for the Health Care Operations activities of the other Covered Entity that receives the PHI, only if all of the following requirements are met:

---

<sup>1</sup> SHIEC proposed a definition of Community Health Information Organizations (CHIOs) in its comments to the Information Blocking Rule as those organizations that are primarily engaged in the business of providing multi-stakeholder, vendor-agnostic health information exchange services that supports interoperability between disparate information systems in a defined community/geographic area.



**S**trategic  
**H**health  
**I**nformation  
**E**xchange  
**C**ollaborative

- Each Covered Entity either has or had a relationship with the Individual who is the subject of the PHI being requested;
- The PHI pertains to such relationship; and
- The disclosure is for a purpose listed in paragraph (1) or (2) of the definition of Health Care Operations, or for the purpose of health care fraud and abuse detection or compliance.

45 C.F.R. § 164.506(c)(2). Business Planning and Development appears in paragraph (5) of the definition of Health Care Operations. 45 C.F.R. § 164.501. Consequently, Covered Entities cannot receive PHI from other Participants and Participants Members under the Common Agreement if the Covered Entity receiving the PHI desires to use it for the Covered Entity's own Business Planning and Development or if the receiving entity is not a Covered Entity (or Business Associate receiving it on behalf of a Covered Entity). SHIEC thus questions the utility of including this as an Exchange Purpose, and believes that the definitions of Business Planning and Development and Exchange Purposes in the MRTCs do not fully alert Participants and Participants Members of the legal restrictions of this use case, particularly Participants and Participants Members who might not be subject to HIPAA.

### **iii. Impact of ONC Information Blocking Rule and Question of Need to Limit Disclosure of EHI Beyond What is Required by Law**

The approach described above (i.e., allowing QHINs, Participants and Participant Members to exchange EHI to the fullest extent permitted under Applicable Law ) is also more consistent with ONC's proposed Information Blocking Rule. The proposed rule seems to prohibit any limitation on sharing of EHI beyond what is required by Applicable Law, unless another exception applies. It is unclear to SHIEC whether an agreement that limits Exchange Purposes beyond what is required by existing privacy laws falls within an exception to the proposed rule, or if participating in the Common Agreement under the restricted Exchange Purposes may subject QHINs, Participants and Participant Members to charges of information blocking and steep fines.

The proposed MRTCs also appear to conflict with the proposed Information Blocking Rule in other ways. For instance, the MRTCs propose to





**S**trategic  
**H**health  
**I**nformation  
**E**xchange  
**C**ollaborative

restrict future uses and disclosures of EHI, unless an exception applies. ONC has given downstream restrictions on the use and disclosure of EHI as an example information blocking. See 84 Fed. Reg. 7424, 7552 (Mar. 4, 2019) (giving as an example a participation agreement that prohibits entities that receive EHI through a HIN from retransmitting it in certain circumstances). SHIEC is concerned that the current drafting of §§ 2.2.2, 7.2 and 8.2 (Permitted and Future Uses of EHI) will unintentionally implicate the proposed information blocking rule, if the proposed rule is finalized.

Moreover, SHIEC questions whether it is necessary for the MRTCs to limit future uses and disclosures beyond what is required by existing privacy laws. One of the six listed exceptions is for uses and disclosures that are “otherwise permitted by Applicable Law.” MRTC §§ 2.2.2, 7.2 and 8.2, “Applicable Law” is broadly defined as “[a]ll applicable federal or state laws and regulations then in effect.” MRTC § 1. This broad exception seems to undermine the MRTC’s limitation on future uses and disclosures. SHIEC suggests instead adopting an approach similar to the one used by PCDH, in which recipients of EHI under the Common Agreement may use and disclose EHI subject to Applicable Law (and whatever other agreement or policies/procedures might apply to that recipient’s use of EHI).

### **C. Operations and Agreements Outside of the Common Agreement**

SHIEC respectfully requests that ONC include express non-exclusivity and residual authority provisions that are applicable to QHINs, Participants and Participant Members. Specifically, such clauses should clarify the following:

- The Common Agreement is not an exclusive agreement.
- Nothing in the Common Agreement shall be construed to preempt, nullify or preclude a QHIN, Participant or Participant Member from performing under, or impairing any rights that they may have under, any other contract or arrangement.
- QHINs, Participants and Participant Members retain the authority to enter into contracts or arrangements outside of the Common Agreement.
- QHINs retain the authority to operate as a non-QHIN with respect to other services it may offer outside of the Common Agreement.



**S**trategic  
**H**health  
**I**nformation  
**E**xchange  
**C**ollaborative

SHIEC also seeks further clarification regarding HINs that wish to become a QHIN while continuing to operate business lines separate from data sharing that might occur under the Common Agreement. For example, may the QHIN Designation apply to only the portion of the entity seeking the QHIN Designation? Because many QHIN obligations in § 2 are tied to EHI without limitation, SHIEC respectfully requests that:

- § 2 be amended to clarify that the obligations apply to only the EHI transmitted between QHINs under the Common Agreement; and/or
- The definition of EHI be amended to clarify that it applies to Electronic Protected Health Information that is electronically transmitted between and among QHINs, Participants and Participant Members under the Common Agreement.

Likewise, SHIEC requests that § 4.2 (Disclosures for Specific Purposes) be revised to clarify that the reports and information covered by subsections (i) and (ii) is limited to events involving the operation of the QHIN. Subsections (iii) and (iv) already contain this limitation.

Finally, SHIEC seeks clarification regarding the appropriate contractual relationship between a HIN designated as a QHIN and that HIN's participants (e.g., the health care providers and health plans that participate in the HIN) who desire to participate in the QHIN. In this circumstance, will the QHIN execute Participant-QHIN Agreements with its participating health care providers and health plans? Although the definitions of "QHIN," "Participant-QHIN Agreement," "Participant Member Agreement," "Participant Member," and "Participant" seem to require this particular contractual relationship (i.e., execution of a Participant-QHIN Agreement), the overarching structure of the Common Agreement seems to anticipate the something different. Specifically:

- Common Agreement between QHINs (i.e., a HIN) and the RCE;
- Participant-QHIN Agreements between QHINs and other HINs (e.g., Participants); and
- Participant Member Agreements between HINs (i.e., Participants) and their Participant Members (e.g., health care providers and health plans).



**S**trategic  
**H**health  
**I**nformation  
**E**xchange  
**C**ollaborative

SHIEC endorses this approach for several reasons. First, the requirements for Participant-QHIN Agreements are similar to, but different from, Participant Member Agreements. Compare MRTC § 2 with § 7. Likewise, the obligations imposed on Participants are similar to, but again different from, obligations imposed on Participant Members. Compare MRTC § 7 with § 8. For example, QHINs and Participants are required to comply with mandatory updating provisions (see §§ 2.2.6, 7.22), certain minimum obligations (§§ 2.2.7, 7.24) and onboarding requirements (§§ 2.2.8, 7.23), whereas Participant Members are not. Consequently, health care providers/health plans that contract directly with a QHIN under a Participant-QHIN Agreement (versus indirectly through another HIN via a Participant Member Agreement) will be subject to greater obligations. SHIEC is not aware of any policy reasons for why such providers/plans should be subject to greater obligations simply because they contract directly with a QHIN, unless the provider/plan operates a HIN.

SHIEC thus respectfully suggests that the contractual framework for TECCA be further simplified as follows:

- Participant-QHIN Agreements will be between QHINs and entities that qualify as HINs. This will require changing the definition of “Participant” to be “a HIN, regardless of whether the HIN is a Covered Entity or a Business Associate, that has entered into a Participant-QHIN Agreement to participate in a QHIN.” The definition of HIN could be further revised to clarify that health IT developers, health systems, health plans, and/or federal agencies may qualify as a HIN.
- Participant Member Agreements will be between either: (i) Participants in a QHIN and Participant Members; or (ii) QHINs and Participant Members. To facilitate this change, Participant Member must be defined as “a natural person or entity, regardless of whether the person or entity is a Covered Entity or Business Associate, that has entered into a Participant Member Agreement to use the services of a HIN that is a QHIN or Participant to send and/or receive EHI, but not an Individual exercising his or her right to Individual Access Services.”



**S**trategic  
**H**Health  
**I**nformation  
**E**xchange  
**C**ollaborative

This framework will permit a QHIN to continue operating and providing services as a HIN, without imposing additional obligations on its participating health care providers and health plans by virtue of its designation as a QHIN.

#### **D. Timeline for Implementation of Common Agreement**

TEFCA Draft 2 proposes an eighteen-month timeline for QHINs to update agreements and technical requirements; SHIEC requests ONC extend this timeline to twenty-four months or consider implementing a mechanism whereby a provisional QHIN can receive an extension for good cause. ONC recognizes that to implement the obligations in the Common Agreement, data sharing agreements between QHINs and Participants and Participants and Participant Members will need to be amended to incorporate the mandatory requirements for data exchange. Furthermore, Organizations will need to time design and develop technical infrastructure to meet the requirements. More time to complete required contractual amendments and technical development will benefit all participant categories and will increase compliance and participation. Therefore, SHIEC respectfully requests that there be a minimum of two years to amend agreements and would prefer a non-binding window.

#### **E. Meaningful Choice**

SHIEC strongly supports an Individual's right to exercise Meaningful Choice regarding how their EHI is shared under the Common Agreement. However, the state of current technology will prevent QHINs, Participants and Participants Members from meeting their obligations to communicate an Individual's choice through the QHIN network. Moreover, the notification obligation and proposed time frame for giving notification may conflict or be inconsistent with existing state laws regarding an Individual's right to opt out of participating in a HIN.

In jurisdictions that offer opt out options to Individuals, the common practice is to implement the opt out at the local/state level and to not share an opted-out Individual's EHI through any exchange modality, unless required by Applicable Law. ONC could adopt a similar approach for TEFCA. This would



**S**trategic  
**H**ealth  
**I**nformation  
**E**xchange  
**C**ollaborative

require removing the notification requirement and replacing it with an acknowledgment that due to an Individual’s exercise of his or her Meaningful Choice and/or Applicable Law, Participants and Participant Members may be prohibited from sending EHI about certain Individuals and/or may be prohibited from acknowledging whether EHI is maintained for such Individuals. This approach has the added benefits of removing conflict and inconsistency with existing state opt out laws and maximizing the flexibility with which Individuals may exercise an opt out right.

Additionally, SHIEC respectfully requests that clarifying language be added to §§ 6.1.5, 7.6 and 8.6 (Written Privacy Policy) regarding how QHINs, Participants and Participant Members are required to communicate to Individuals their right to exercise Meaningful Choice. As currently drafted, these Sections require QHINs, Participants and Participant Members “to publish and make publicly available a written notice” that includes (among other things) a description of how to exercise Meaningful Choice. Consistent with §§ 2.2.3, 7.3 and 8.3 (Individual Exercise of Meaningful Choice), a statement should be added that posting the written privacy policy on a public website is sufficient to satisfy this obligation.

#### **F. Breach Notification Requirements**

SHIEC is supportive of applying the HIPAA breach notification requirements to any non-Covered Entities that opt to participate in the Common Agreement.

#### **G. Minimum Security Requirements**

SHIEC is agreeable with the requirements set forth for security. However, QHINs are to evaluate their security program annually, while Participants and Participant Members are not being held to the same standard. Participants can be health IT vendors, health systems, payors or HIEs with the wherewithal to do annual risk assessments, etc. A framework whereby certain organizations use and disclose EHI but are not held to the same information security risk management standards would fail to meet the goal of “trust” for secure exchange of patient data and could lead to an uneven vulnerability landscape.



**S**trategic  
**H**ealth  
**I**nformation  
**E**xchange  
**C**ollaborative

#### **H. No EHI Used or Disclosed Outside the United States**

SHIEC agrees with the proposed limitations on exchanging data outside the U.S., particularly agrees with requirements to host data within the U.S. (i.e., not store data outside of the country). This limitation is also in line with existing contracts for many industry stakeholders.

With the above in mind, however, SHIEC requests that ONC consider the increasingly international lifestyle of Americans and whether limited sharing of data offshore (e.g. to combat infectious disease outbreaks) may be appropriate in the future.

#### **I. Security Labeling**

Draft 2 is currently silent on whether security labels may or must be placed on sensitive categories of EHI to comply with state and federal privacy laws that are more restrictive than HIPAA, such as substance use disorder information protected by 42 C.F.R. Part 2. Many states do not require special labeling of sensitive EHI, and data segmentation at the point of data entry or subsequent identification of such EHI is not required by current federal law. Moreover, the technology available for data segmentation and segregation is not fully developed or widely used. Thus, mandating the use of security labeling at this point in time will only serve to depress EHI exchange under the Common Agreement. SHIEC thus requests that the ONC not go beyond existing federal and state law in this area.

#### **J. Monitoring Compliance**

SHIEC supports requiring that QHINs and Participants use reasonable steps to confirm compliance with Common Agreement obligations. However, it is unclear what ONC considers to be reasonable steps. In many circumstances, a QHIN or Participant will lack any actual control or oversight authority over the Participant Member. Monitoring programs thus may be limited to automated or manual auditing programs that identify aberrant uses of the network. Such a compliance program could be addressed through the MRTC's auditing



**S**trategic  
**H**ealth  
**I**nformation  
**E**xchange  
**C**ollaborative

requirements instead of imposing a separate, undefined obligation to monitor compliance. See §§ 6.2.8, 7.11 and 8.11.

Additionally, requiring annual written confirmation of compliance from Covered Entity and Business Associate Participant Members is unnecessary, imposes an undue administrative burden and may have the unintended effect of discouraging participation in QHINs, as Participants face difficulty in amending their Participation Member Agreements to include such requirements. HIPAA already requires such Participant Members to comply with many of the minimum obligations, such as use and disclosure of PHI, security requirements, breach reporting, and Individual access and accounting rights. SHIEC thus respectfully request that this requirement be omitted or required for only Participant Members who are not Covered Entities or Business Associates subject to HIPAA.

### **III. APPENDIX 3 - QHIN TECHNICAL FRAMEWORK**

**A. Definitions:** SHIEC has no specific comments; however, stands ready to support ONC as you finalize definitions.

#### **B. QHIN Exchange Scenarios:**

- **Query scenario:** SHIEC seeks to clarify that this scenario assumes the delivery of data to the origin of the query in an XCA format, meaning that the data can only be displayed and not retained in the originating system. And, thus, a patient initiating this query through an XCA system will not be able to retain the data delivered. Further, some XCA structures only deliver certain kinds of data (i.e., HL7 OR CCD, but not necessarily both and not necessarily in a consolidated format). This is important to understand as the volume of data returned in a query could literally be dozens (or even hundreds) of documents. SHIEC seeks to clarify that this scenario assumes the delivery of data to the origin of the query in an XCA format, meaning that the data can only be displayed and not retained in the originating system. And, thus, a patient initiating this



Strategic  
Health  
Information  
Exchange  
Collaborative

query through an XCA system will not be able to retain the data delivered. Further, some XCA structures only deliver certain kinds of data (i.e. HL7 OR CCD, but not necessarily both and not necessarily in a consolidated format). This is important to understand as the volume of data returned in a query could literally be dozens (or even hundreds) of documents.

- **Message delivery scenario:** This scenario has some of the same limitations as the query scenario described above. There could be dozens of documents delivery in an unconsolidated format.

### C. Functions and technology to support exchange:

- **Certificate Policy:** SHIEC agrees with this section.
- **Secure channel:** SHIEC does not have any comments on this section
- **Sever Authentication:** SHIEC supports the use of authentication for servers. SHIEC supports the addition of the SAML requirement; however, some EHR vendors cannot support the inclusion of this data content so adding the SAML should be encouraged but not required.
- **User Authentication** SHIEC supports the use of authentication for users. SHIEC supports the addition of the SAML requirement; however, some EHR vendors cannot support the inclusion of this data content so adding the SAML should be encouraged but not required.
- **Authorization and Exchange purpose:** HIEs are uniquely and singularly best suited to appropriately verify whether an entity is eligible to access a requested network or service. Every HIE is keenly aware of its own consent policies as well as its local and state laws and regulations for sharing. This is not true of other types of organizations that might apply to be a QHIN. Other types of organizations are not as well-versed (if at all) on the operational





Strategic  
Health  
Information  
Exchange  
Collaborative

and technical lift that is required to accomplish authorization for proper exchange access for specified purposes.

- **Query:** SHIEC suggest that ONC utilize a technical workgroup composed of TEFCA participants to develop these standards further. SHIEC supports the query requirements; however, suggests that ONC utilize a technical workgroup composed of TEFCA participants to develop these standards further.
  - Specific to ONCs request on Comment #4 (i.e., whether the RCE should develop specific technical guidance to address variations in implementation workflows), SHIEC supports the RCE providing more prescriptive requirements on this item. However, requirements that impact the EHR and its ability to provide data, should come with consequences for not being about to support the workflow with a QHIN.
  - Specific to ONCs request on Comment #5 (i.e., whether the QTF should specify which queries/parameters a QHIN must support), SHIEC believes that the QTF should provide specificity on the query parameters.
  - Specific to ONCs request on Comment #6 (i.e., the appropriate standards for implementation of discrete data queries, such as emerging IHE profiles leveraging RESTful APIs and/or use of HL7 FHIR), SHIEC believes that these additional IHE profiles are good but not mature enough at this time to make a requirement.

Additionally, SHIEC strongly encourages ONC to work with CMS to add to the Promoting Interoperability requirements that EHR vendors must support the capability to include more granular data in response to queries for discrete data (e.g., a request for all clinical documents about a patient that contain a specific medication or laboratory result). These data content items are the most highly requested from providers, yet not required in the Meaningful Use Stage 2 criteria for EMR certification.



Strategic  
Health  
Information  
Exchange  
Collaborative

- **Message Delivery:** SHIEC does not have any comments on this section.
- **Patient Identity Resolution:** SHIEC believes there is a fundamental need for robust patient matching nationwide. SHIEC supports various forms of querying for a patient (including broadcast and targeted queries), but strongly believes that ONC must set measurable, common matching standards (e.g., thresholds for accuracy) to ensure nationwide. SHIEC supports a broad set of patient matching identifiers and multiple methods to enable successful matching, but believes that ONC must institute measurable standards to ensure organizations are implementing effective and efficient mechanisms to identify and locate patients. As mentioned above, SHIEC welcomes the opportunity to work together with ONC to experience and best practices to develop nationwide standards.
- **Record location:** SHIEC supports continuing to allow a variety of methods to perform record location based upon existing technical capabilities, but supports ONC's efforts to find a workable solution to standardize record location in the future.
- **Directory Services:** SHIEC supports continuing to allow a variety of methods to perform directory services based upon existing technical capabilities, but supports ONC's efforts to find a workable solution to standardize directory services in the future.
- **Individual Privacy Preferences:** SHIEC believes that in order to appropriately select and/or specify a for Meaningful Choice, it would be better to focus on a national consent policy. SHIEC believes that an act of Congress is necessary to help clear the way for an effective policy and requirement on this matter.



Strategic  
Health  
Information  
Exchange  
Collaborative

- **Auditing:** SHIEC supports the IHE standards for auditing.
- **Error Handling:** SHIEC strongly supports that the QTF specify the set of error messages and their contents for interactions for QHINs.