MISSOURI HEALTH CONNECTION

June 17, 2019

Missouri Health Connection
555 E. Green Meadows, Suite 9
Columbia, MO 65201

The Office of the National Coordinator (ONC) for Health Information Technology
U.S. Department of Health & Human Services
330 C Street SW, Floor 7
Washington, DC 20201

SUBJECT: Trusted Exchange Framework and Common Agreement (TEFCA) Version 2

RE: Missouri Health Connection Response to TEFCA Version 2

Dear Dr. Rucker:

Missouri Health Connection (MHC) is pleased to provide you with the following feedback, comments and suggestions regarding the release of the draft TEFCA Version 2.

MHC is the only secure, statewide, private, non-profit HIE in Missouri. MHC provides over 7,000 clinicians, hundreds of clinics and community health centers and more than 75 hospitals and health plans with access to comprehensive patient health records for more than 22+ million patients. MHC's services are designed to support health care clinicians and payors with more complete and accurate patient health records. The electronic exchange of health records in the MHC network, enables clinicians to quickly and securely access and receive real-time comprehensive patient health records resulting in improved quality of health care delivery by coordinating care, reducing preventable errors and avoiding treatment duplication. No matter where a patient goes for care, MHC supports its participating health care stakeholders, by providing an up-to-date, comprehensive, longitudinal health record including clinical and claims data. MHC's service solutions improve health care outcomes and quality by supporting access to aggregated patient information to identify gaps in patient care and provide more clinical data to clinicians and care coordinators for enhanced clinical decision making.

As a national leader in the HIE market, MHC specializes in data normalization and robust data exchange. MHC serves as an unbiased, vendor agnostic, trusted health information technology solution that provides an advanced technological framework enabling access to comprehensive electronic patient records across from multiple data sources in real-time. As an interoperability specialist in clinical and claims data exchange, MHC has connected hundreds of disparate data sources including health care clinicians, regional, state and national HIEs, health plans, and accountable care organizations (ACOs). As the Midwest gateway, MHC is a nationally identified

HIE gateway in the CMS supported Patient Centered Data Home initiative sponsored by the Strategic Health Information Exchange Collaborative (SHEIC), facilitating the exchange of clinical information across the country by connecting to more than 40 other HIEs. Additionally, MHC is also connected to Veterans Administration and the Department of Defense.

MHC, as an HIE, uniquely provides community-level identity resolution and linking of data beyond certified EHRs, including data from pharmacies, post-acute care, behavioral health, social services, and many others. MHC's mission focuses on quality patient care, improving health outcomes, innovations to improve efficiencies and reducing costs for our Participants. Members of MHC's HIE network receive innovative, cost effective strategic services that provide a return on investment by transforming the delivery of care. Additionally, MHC strives to support ONC both as a partner in, and a resource for advancing interoperability.

To that end, the following comments represent MHC's position on the provisions and recommendations posed under TEFCA and MHC offers various recommendation to achieve nationwide interoperability.

Generally, MHC supports the development of a framework for nationwide interoperability. As discussed in detail below, MHC requests that ONC particularly consider the following:

- The importance of engaging various stakeholders (including MHC 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

- The fundamental need for robust reliable patient matching is a centralized master patient index (MPI), like what and HIEs provide, which is not met by relying on broadcast queries as envisioned in Draft 2. MHC supports patient query that utilizes an MPI. Also, MHC strongly believes that ONC must set measurable, common matching standards (i.e. thresholds for accuracy) to ensure proper and successful nationwide interoperability. With substantial matching experience, MHC and SHIEC would welcome the opportunity to engage further with ONC to establish workable national standards.

- The result of these efforts delivers a C-CDA that will be adopted by caregivers. In our experience, this is a single consolidated document with links for easy navigation.

- Additionally, MHC recommends that the ONC work to develop more stringent oversight on electronic health record (EHR) vendors to ensure compliance with the interoperability standards that support the goals of TEFCA Version 2. Much of what is being requested in the Common Agreement, the Minimum Required Terms and Conditions (MRTCs),

Additional Required Terms and Conditions (ARTCs) and the technical framework of the QHINs has direct links to EHR systems that much be able to produce and export data and content in such a way to make a QHIN successful; thus, the RCE successful. MHC believes that ONC, by itself and in cooperation with other federal agencies, needs to be able to have the ability to enforce standards on EHR vendors as well as be able to assert penalties for non-compliance.

MHC appreciates this opportunity to provide comment to the TEFCA and is happy to further discuss our comments, concerns and suggestions with the ONC at any time. Please feel free to reach out to MHC directly and contact Angie Bass at 573-777-4550 or ABass@MissouriHealthConnection.org.

Sincerely,

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Missouri Health Connection Comments on TEFCA Version 2

I. TRUSTED EXCHANGE FRAMEWORK

A. Regional Coordinating Entity (RCE).

MHC believes that the *roles and responsibilities of the RCE should reside at and with the ONC*. Government oversight is necessary for accountability and success for nationwide interoperability when there are multiple stakeholders involved. MHC believes that the ONC should reconsider its position to outsource the RCE responsibilities and instead serve as the trusted, non-conflicted governing body that will provide proper deployment and enforcement of the TEFCA.

However, if ONC elects not to serve in the RCE role, then MHC provides the following and remaining comments on TEFCA Version 2 in this letter with the assumption that ONC will outsource the RCE to a third-party entity.

MHC 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. MHC 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, MHC requests that ONC consider whether changes to the proposed framework may be appropriate. Specifically, *MHC recommends that ONC consider creating a steering committee (composed of federal and state agencies, HIEs, health care providers and other relevant stakeholders) 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 would 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, MHC and SHIEC welcome the opportunity to provide guidance to ONC as a participant on a steering committee, or in any way that will improve nationwide interoperability.

Finally, MHC 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, MHC recommends that ONC continue to develop a regulatory framework that will ensure that vendors are able to produce and export data and content in such a way to make parties to the Common Agreement, and the framework, successful.

B. QHIN

MHC supports the revisions to the definition of a Qualified Health Information Network (QHIN) in TEFCA Draft 2, though MHC recommends adding more specific requirements around a QHIN's ability to conduct patient matching and

person location. Specifically, MHC strongly believes that ONC must set measurable, common matching standards (e.g. thresholds for accuracy) to ensure nationwide interoperability. MHC stands ready to offer its expert guidance to ONC on the value of robust patient matching and person location capacity. MHC 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 resulting in thorough and consistent patient matching, locating their encounter data and support of various consent models.

Additionally, MHC supports a probationary "provisional QHIN" step in the QHIN application process. MHC also sees value in collaborating with a cohort to ensure readiness of the infrastructure. *MHC would appreciate ONC expanding on the requirements of provisional QHIN, specifically the application of the common agreement to a provisional QHIN).* MHC also requests a more clear explanation of 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 Members when it begins exchanging data provisionally? Why not eliminate 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 MHC would appreciate clarification on the following questions:

- *Is a vendor, who on receives electronic health information (EHI) from a Health Information Network (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, like such a Participant Member's responsibilities for its authorized users?* An all or nothing approach could thwart the success of promoting EHI exchange if some entities are not willing to agree to the terms of the Participant-QHIN Agreement or Participant Member Agreement.
- *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?* If the HIN doesn't have a current process for delivering data to individuals, and their policies prohibit such, do they have to respond to individual requests?

- *Can an entity be a Participant in more than one QHIN? MHC 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.
- Will there be a limit on the number of QHINs that will be approved? MHC believes that there should be a reasonable number of QHINs to appropriately be able to complete nationwide interoperability; however, too many QHINs could cause confusion, frustration and duplicative efforts in the market.

II. COMMON AGREEMENT & MINIMUM REQUIRED TERMS AND CONDITIONS

A. Exchange Modalities. MHC 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, MHC believes that requiring QHINs to support QHIN Broadcast Query (as currently defined) is premature and will likely exclude various networks that already effectively sharing 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, *MHC proposes making the QHIN Broadcast Query optional.*

Furthermore, MHC questions the viability of a QHIN Broadcast Query to meet nationwide-interoperability needs. Specifically, MHC 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, *MHC 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, MHC would gladly provide any additional assistance to ONC in developing an appropriate matching framework.

Additionally, MHC 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, *MHC 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.

B. Exchange Purposes. MHC supports allowing QHINs, Participants and Participant Members to exchange EHI to the fullest extent permitted under Applicable Law. *MHC further supports permitting Participants and Participant Members to further limit the purposes for which they will exchange EHI to reflect their community's business practices and privacy concerns.* MHC believes that providing for this flexibility, while honoring the autonomy of Participants and Participant Members, will ensure the greatest participation in TEFCA and sharing of EHI consistent with individual and community privacy expectations. (For example, a health care provider should be able to freely elect to be a subscribing member of their local or regional HIE and that HIE should be allowed to collect fees for their services provided to the health care provider.)

i. **Payment.** MHC 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 from HIEs, and MHC is confident that the use of the common agreement among payers will be critical to its success. MHC 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 and health care providers. For this reason, *MHC supports allowing QHINs, Participants and Participant Members to exchange EHI to the fullest extent permitted under Applicable Law.*

ii. **Business Planning and Development**. MHC 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) 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 the following requirements are met:

- 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). *MHC 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. If this Exchange Purpose is adopted, then at the very least the requesting QHIN should be required to deliver a certification that the requesting entity has a Business Associate relationship with the Covered Entity that intends to use EHI for Business Planning and Development purposes, as any other disclosure would seemingly run afoul of the HIPAA regulations, unless a HIPAA-compliant authorization is first obtained.*

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 MHC 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 MRTC proposes to 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). MHC 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, *MHC 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. MHC suggests instead adopting an approach like 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.** MHC 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.

MHC 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 Designation?* Because many QHIN obligations in § 2 are tied to EHI without limitation, *MHC 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, *MHC 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, *MHC 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 contractual relationship, the overarching structure of the Common Agreement seems to anticipate the following:

- 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 (e.g., Participants) and their Participant Members (e.g., health care providers and health plans).

MHC endorses this approach for several reasons. First, the requirements for Participant-QHIN Agreements are like but different from Participant Member

Agreements. Compare MRTC § 2 with § 7. Likewise, the obligations imposed on Participants are like 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 Participation Member Agreement) will be subject to greater obligations. MHC 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.

MHC thus respectfully suggests that the contractual framework for TEFCA 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 Participants 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."

  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 Version 2 proposes an eighteen-month timeline for QHINs to update agreements and technical requirements. 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. *MHC respectfully requests that there be a minimum of two years to amend agreements and would prefer a non-binding window.* Negotiating agreements, particularly with large systems can take months, and sometimes more than a year. More time to complete required contractual amendments will benefit all participant categories and will increase compliance and participation.

E. Meaningful Choice. MHC 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 consent 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 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, *MHC 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 enough to satisfy this obligation.

Furthermore, and for example, TEFCA Version 2 as proposed, impacts MHC's current consent-to-share model. And it is unlikely that any QHIN could adequately support multiple consent models. It does not seem that TEFCA Version 2 provides a clear or great solution for QHINs to address this issue. HIEs that wish to be a QHIN will be wholly reliant on the consent that is obtained by a requesting entity such that the ability to filter sensitive information (as determined by the indicated Exchange Purpose for each transaction) will be necessary. In other words, and HIE will only ever be able to disclose information for which no consent is necessary for the intended purpose, unless adequate consent or authorization from the requesting QHIN is received.

F. Breach Notification Requirements. MHC is supportive of applying the HIPAA breach notification requirements to any non-covered entities that opt to participate in the Common Agreement; however, requests that the definition of "Breach" be clarified to emphasize that any incident that meets the definition of the same term 45 CFR 164.402 within the confines of a Participant's or a Participant Members' internal operations and which does not implicate Common Agreement obligations,

is not considered a "Breach" requiring notification pursuant to the Common Agreement. The definition of "Breach" seems overly broad and could be construed as requiring a Participant to provide notice under these agreement for something that occurs internally if it involves EHI that that Participant contributed or exchange through the framework.

G. **Minimum Security Requirements.** MHC 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 major health-IT vendors, major 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.

H. **No EHI Used or Disclosed Outside the United States.** MHC agrees with the proposed limitations on exchanging data outside the U.S., and for some members, such a limitation will facilitate compliance with existing contracts that contain similar restrictions. However, MHC requests that ONC explicitly permit Participants and Participant Members to use or disclose EHI outside of the United States, in accordance with their own internal policies and Applicable Law, for any future uses and disclosures of EHI. The rationale for this request is to not thwart health care providers from being able to take advantage of the digital health innovations that are taking place on a global level.

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 now will only serve to depress EHI exchange under the Common Agreement. *MHC thus requests that the ONC not go beyond existing federal and state law in this area.* Also, *MHC strongly encourages additional compliance checks on EHR vendors to meet the industry standards set and identified in TEFCA Version 2 for entities like HIEs to be able to facilitate Security Labeling.*

J. **Monitoring Compliance.** MHC 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 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. MHC 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. MHC supports the definitions related to the QTF.

B. Data Delivery Scenarios.

Query scenario: MHC 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 retuned in a query could literally be dozens (or even hundreds) of documents. MHC 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 retuned 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. There could be dozens of documents delivery in an unconsolidated format. This scenario has some of the same limitations as the query scenario. There could be dozens of documents delivery in an unconsolidated format.

C. Functions and technology to support exchange.

Digital certificates: MHC supports the certificate requirements.

Secure channel: MHC supports the secure channel requirements.

Server and User Authentication: MHC supports the use of authentication for both servers and users. MHC 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 ideal but not required.

Authorization and Exchange purpose: MHC would like to acutely draw ONC's attention that HIEs are best suited to appropriately verify whether and 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. Not all data sharing organizations that would likely apply to be a QHIN are as well versed, if at all, on the lift that is required to operationally and technologically to accomplish authorization for proper exchange access for specified purposes.

Query: MHC 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 related to whether the RCE should develop specific technical guidance to address variations in implementation workflows, MHC does support the RCE providing more prescriptive requirements on this item. However, requirements that impact the EHR and its ability to provide data, should come with consequence for not being about to support the workflow with a QHIN.
- Specific to ONCs request on Comment #5 related to whether QTF should specify which queries/parameters a QHIN must support, MHC does believe that the QTF should provide specificity on the query parameters.
- Specific to ONCs request on Comment #6 related to appropriate standards to consider for implementation to enable more discrete data queries, such as emerging IHE profiles leveraging RESTful APIs and/or use of HL7 FHIR, MHC believes that these additional IHE profiles are good but not mature enough at this time to make a requirement. Additionally, MHC 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.

Patient Identity Resolution: MHC believes there is a fundamental need for robust patient matching nationwide. MHC 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. MHC 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, MHC welcomes the opportunity to work together with ONC to experience and best practices to develop nationwide standards.

Record Location: MHC 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: MHC 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: MHC believes that to appropriately select and/or specify a for Meaningful Choice, it would be better to focus on a national consent policy. MHC believes that an act of Congress is necessary to help clear the way for an effective policy and requirement on this matter.

Auditing. MHC supports the IHE standards for auditing.

Error Handling. MHC strongly supports that the QTF specify the set of error messages and their contents for interactions for QHINs.

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