AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

June 17, 2019

Office of the National Coordinator for Health Information Technology

Final Comments to be Submitted Electronically to: **HealthIT.gov**

RE: Public Comment on ***Trusted Exchange Framework and Common Agreement Draft 2***

Dear Office of the National Coordinator for Health IT:

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on ONC's ***Trusted Exchange Framework and Common Agreement Draft 2*** that was developed in response to the 21st Century Cures Act. As a member organization with more than 600 members representing 77 Public Health organizations, 12 businesses and sponsors, and 512 individuals from Immunization Information System (IIS) programs and partners, these comments represent a broad perspective on federal actions that affect immunization programs across the country, particularly as they relate to issues that impact the interoperability of immunization records. At the point of clinical care, an IIS provides consolidated immunization records and forecasts to support clinical decisions. At the population level, an IIS provides aggregate data and information on vaccinations for surveillance, program operations and public health action. End users of these data include private and public health care providers, schools, childcare facilities, Medicaid and other health payers, and consumers, among others.

We appreciate the opportunity to provide comments on this important step forward in the nationwide exchange of health data. IIS are present and active in every state and several territories and municipalities throughout the country. As a community of IIS programs and partners, data exchange, data consolidation and data use are foundational to our purpose.

In 2014, the Journal of Public Health Management and Practice[1] published the findings of a Community Guide Systematic Review that stated:

Findings from 240 articles and abstracts demonstrate IIS capabilities and actions in increasing vaccination rates with the goal of reducing vaccine-preventable disease.

[1] Groom, H. et al. (2014). Immunization Information Systems to Increase Vaccination Rates: A Community Guide Systematic Review. *Journal of Public Health Management Practice, 21*(3):227–248. Retrieved from https://www.thecommunityguide.org/sites/default/files/publications/vpd-jphpm-evrev-IIS.pdf

As a result of this review, the Community Preventive Services Task Force recommended use of IIS on the basis of strong evidence of effectiveness in increasing immunization coverage rates.

One reason for the broad success of IIS in general, and IIS-Electronic Health Record (EHR) interoperability specifically, is the early alignment with standards. Standards have long been recognized and adopted across the IIS community. In 2016, 91% of IIS jurisdictions used HL7 (Health Level Seven) version 2.5.1 messaging to receive vaccination histories from providers and return acknowledgement messages, while 67% of jurisdictions had an IIS that received and responded to queries from providers for immunization histories and forecasts, according to an MMWR article published using the CDC IIS Annual Report data.[2] This same report noted that 78% of jurisdictions had an IIS that could transmit immunization data using Simple Object Access Protocol (SOAP), the CDC-endorsed transport standard for the exchange of immunization information. This community-wide alignment with standards is being supported and validated through AIRA's Measurement and Improvement Initiative as well.[3] Meaningful use and the adoption of Certified Electronic Health Record Technology (CEHRT) by the EHR community have helped to accelerate the pace of interoperability across IIS and EHRs.

AIRA's general comments on the Draft Trusted Exchange Framework and Common Agreement are presented below, and more detailed comments are presented on the following pages.

Significant Comments in Support:

The IIS community strongly supports QHIN Message Delivery, or the addition of a push-based exchange modality, to TEFCA Draft 2. This is a critical component of interoperability for IIS specifically, and for public health more generally. It Is clear that the authors of TEFCA recognize the important role public health plays in the health care ecosystem, and we appreciate the intentional inclusion of public health in the TEFCA vision.

In particular, we found the organization of levels of standards articulated by TEFCA Draft 2 to be especially helpful. Beginning with those standards adopted by HHS, followed by those proposed standards through the ONC Certification Program, followed by ISA creates a helpful stair-step approach to leveraging and reconciling multiple standards.

The materials provided by ONC are clear, easy to navigate, and helpful for understanding the scope and focus of TEFCA. In particular, the User's Guide is especially accessible for those seeking to comprehend their place in the TEFCA environment.

[2] https://www.cdc.gov/mmwr/volumes/66/wr/mm6643a4.htm
[3] http://www.immregistries.org/initiatives/measurement-and-improvement-initiative

Significant Comments of Concern/Recommendations:

We recognize that under the HIPAA Privacy Rule, individuals have a right to view or obtain a copy of their PHI from Covered Entities. We are concerned, however, about the inclusion of a corresponding requirement for non-HIPAA entities that elect to participate in the Common Agreement. Some public health laws and rules do not allow individuals to access their own data, or they restrict how access is obtained (Example: a state rule requires the patient to come in person with photo ID for identity proofing). We request that public health be provided a specific exemption from this requirement as HIPAA does. This will ensure that data continues to flow smoothly, and that the public health needs supported by interoperability continue to be met.

Although the concept of Meaningful Choice (defined as the individual's choice with respect to the use or disclosure of EHI) begins to address consent issues, our concern is that it does not necessarily recognize or account for the complexity of consent. Public Health reporting mandates, opt-in/opt-out provisions, age-based requirements for reporting, age-based consent for inclusion, automated vs. manual reporting, and modified or rescinded consent over time all add complexity to a nation-wide approach to interoperability.

Compounding these challenges is the fact that exchange may include multiple hops, with the potential for data to be stored at multiple locations. Given the current environment with bidirectional exchange, each of these hops will be required to be made via a return message as well. All this adds complexity to an already complex set of functions when consolidating accurate and complete immunization records. We feel these specific issues and others related to the intersection of law/policy and individual choice could be further articulated in TEFCA Draft 2.

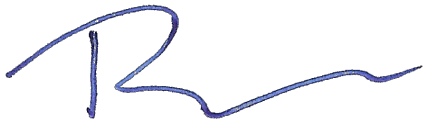
Perhaps our most significant question is related to the fundamental approach for how public health will tie in with the backbone of TEFCA. The document speaks to QHIN-to-QHIN exchange, but in all likelihood, IIS will be operating at the Participant Member level. It is not clear how these data exchange pathways will be standardized, adopted, and sustained over time to fully support nation-wide exchange.

The following table includes further detailed comments by section, called out by page number where appropriate. Please contact Mary Beth Kurilo, AIRA's Policy and Planning Director, with any questions: mbkurilo@immregistries.org.

AIRA greatly appreciates the efforts of ONC to further interoperability across organizations and jurisdictions, and we look forward to supporting our members and partners as they navigate

further exchange both within and outside of the Trusted Exchange Framework and Common Agreement.

Sincerely,



Rebecca Coyle MSEd, Executive Director
American Immunization Registry Association (AIRA)

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Comments on the Trusted Exchange Framework and Common Agreement, Draft 2

Section/ Page Number	Excerpt	Comment
Page 9	ONC will develop the MRTCs, which will consist of mandatory minimum required terms and conditions with which Qualified Health Information Networks (QHINs) may voluntarily agree to comply.	This wording seems ambiguous. Is adherence to the MRTCs really voluntary for QHINs? Clarification would be helpful.
Page 10	The TEF and the Common Agreement follow a "network of networks" structure, which allows for multiple points of entry and is inclusive of many different types of health care stakeholders. Such stakeholders include, but are not limited to: • …Public Health Agencies…	We appreciate the continued explicit inclusion of public health as a key stakeholder and important contributor to the TEFCA concept.

Section/ Page Number	Excerpt	Comment
Page 14	Additionally, ONC received a number of requests from commenters to include a "push-based" exchange modality in the TEF and the Common Agreement. Commenters noted that push transactions play a vital role in supporting transitions of care and public health use cases and would be necessary to fully support required Public Health reporting. Therefore, ONC has included QHIN Message Delivery, which supports instances where a QHIN sends EHI to one or more QHINs for delivery. We request comment on the inclusion of QHIN Message Delivery and its definition.	We strongly support the addition of the "push" use case to TEFCA Draft 2. This addition will allow Public Health to participate meaningfully and broadly in TEFCA.
Page 14	As such, the TEF, MRTCs, and QTF do not dictate the internal requirements or business structures of QHINs, but rather provide QHINs flexibility to provide different services and support different stakeholders.	While it is important to not micro-manage the activities of QHINs, there may be reason for concern if each QHIN requires adherence to different standards and processes. Some stakeholders, most notably Health IT developers, may need to support participation in multiple QHINs and would be burdened by variations in requirements. We encourage the development of some basic "rules of the road" for intra-QHIN exchanges.

Section/ Page Number	Excerpt	Comment
Page 14	QHIN Targeted Query: a QHIN's electronic request for EHI (sometimes referred to as a "pull") from specific QHINs in the context of the Common Agreement to the extent permitted by the Common Agreement and Applicable Law.	Since IIS consolidate data from many sources over an individual's lifespan, data are constantly changing and being updated. To ensure queries result in the most current and "fresh" record, we would recommend that re-query be considered as a requirement or strongly recommended provision within TEFCA, and that caching data (which could quickly become outdated or "stale") be strongly discouraged.

Page 15	The Exchange Purpose described as Individual Access in TEF Draft 1 has been modified to Individual Access Services, which includes the HIPAA Privacy Rule right for an individual to view or obtain a copy of his or her Protected Health Information from Covered Entities. The Individual Access Services Exchange Purpose now includes a corresponding requirement for non-HIPAA entities that elect to participate in the Common Agreement. We request comment on the scope of these Exchange Purposes.	There is some ambiguity regarding the provisions for Individual Access Services and whether a public health registry is required to respond to such a request if it is unable or unwilling to do so. TEFCA clearly states that a response is not necessary if such a response would be against the law (as it is in some jurisdictions). Normally, response to Individual Access Services requests is based on the requirement under HIPAA for covered entities (CE) and their business associates (BA) to provide a patient with his/her EHI on request; the TEFCA draft (in section 7.14(ii)) makes this requirement to respond incumbent on all participants whether they are CEs/BAs or not. Upon careful read of this section it requires a "direct relationship" between the patient and the registry (see definition on p. 33), which does not exist without an explicit offering of this service by the registry. Therefore, it appears that public health registries who do not explicitly offer patient access services are not required to do so. Perhaps ONC should issue a clarification on this issue. It is important to note that some public health laws and rules do not allow individuals to access their own data or restrict how access is obtained (Example: a state rule requires the patient to come in person with photo ID for identity proofing). We request that

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		public health be provided a specific and explicit exemption from this requirement as HIPAA does. A suggestion is to update 8.21 on page 67 to extend the exemption provided to federal agencies there to state and local agencies.
Page 16	In order to meet the goals of the Cures Act as well as to help address these concerns and encourage robust data exchange that will ultimately improve the health of patients, the Common Agreement requires non-HIPAA entities, who elect to participate in exchange, to be bound by certain provisions that align with safeguards of the HIPAA Rules. This will bolster data integrity, confidentiality, and security, which is necessary given the evolving cybersecurity threat landscape.	It is not clear what this might mean for non-covered entities in Public Health and the Public Health exclusion for HIPAA disclosures – please articulate more fully. We would recommend an explicit exclusion for non-covered entities in Public Health. In addition, if an IIS does provide Individual Access Services, we are not sure this should be subject to HIPAA, as this is a public health function.

Section/ Page Number	Excerpt	Comment
Page 17	Therefore, the MRTCs Draft 2 requires that QHINs, Participants, and Participant Members provide Individuals with the opportunity to exercise Meaningful Choice to request that their EHI not be Used or Disclosed via the Common Agreement, except as required by Applicable Law.	It seems confusing to say that local law supersedes TEFCA, but an entity that participates must abide by their Common Agreement. There is also a lack of clarity about right to opt out vs required reporting laws, and where patient consent is stored. It would be very difficult to reconcile those competing concerns across state lines. These issues suggest that there may be a level of detail not yet identified or addressed in these documents.
Page 19	Labeling shall occur at the highest (document or security header) level.	The ONC proposed rule calls for security labeling at a more granular level. Should these two proposals by harmonized?

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Page 19	Currently, security labels can be placed on data to enable an entity to perform access control decisions on EHI such that only those persons appropriately authorized to access the EHI are able to do so. ONC is considering the inclusion of a new requirement regarding security labeling that states the following: • At a minimum, such EHI shall be electronically labeled using the confidentiality code set as referenced in the HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 (DS4P IG), Part 1: CDA R2 and Privacy Metadata;	It's not clear where/how this HL7 V3 code set would be used in non-V3 EHI exchanges such as V2 or FHIR. Also, please clarify what "at a minimum" means. Are there examples of things that are better than this suggested floor which could be used?
Page 20	• QHINs have 12 months to update agreements and technical requirements. Was changed to: • QHINs have 18 months to update agreements and technical requirements.	We support the longer timeline, and believe it to be more reasonable and attainable.

Section/ Page Number	Excerpt	Comment
Page 20	• QHINs may not charge other QHINs to respond to queries for Individual Access, Public Health, or Benefits Determination. Was changed to: • QHINs may not impose any other fee on the Use or further Disclosure of the EHI once it is accessed by another QHIN.	It is not clear what the implication is if Public Health related queries are not exempted from fees. Does this mean that a Public Health entity may need to pay for access to data held by QHINs and their participants? Does this mean that a Public Health entity may charge users for access to data held by the entity? Given the critically important role Public Health data plays in maintaining healthy populations, we strongly advocate for restoration of the prior wording.
Page 25	Specifically, HINs should first look to use standards adopted by HHS, then those approved by ONC through the proposed standards version advancement process as part of the ONC Health IT Certification Program (Certification Program), and finally, those identified in the ISA. In instances where none of the above references include applicable standards, HINs should then consider voluntary consensus or industry standards that are readily available to all stakeholders…	This schema is helpful to organize adherence to standards in a prioritized order.

Section/ Page Number	Excerpt	Comment
Page 28	To support accurate matching, HINs should agree upon and consistently share a core set of demographic data each time that EHI is requested. Likewise, participants of HINs should ensure that the core set of demographic data is consistently captured for all individuals so that it can be exchanged in a standard format and used to accurately match data.	The issue of patient matching across the healthcare ecosystem continues to be a serious obstacle to interoperability. The description of patient matching for query purposes within the MRTC presents a rather simplistic view of patient matching, with no recognition of the complexity of uncertain matches, multiple matches, and similar issues. The Patient Identity Resolution section of the QTF does detail more expectations of a QHIN in this area but offers no real solutions to the difficulties we all experience.
Pages 9, 10, 34	Pgs. 9-10: This Common Agreement would be based on the TEF noted above and would be comprised of three parts: • MRTCs, ARTCs, and the QHIN Technical Framework But: Pg. 34: The Common Agreement shall consist of (a) the Minimum Required Terms and Conditions, (b) the Additional Required Terms and Conditions, and (c) such other terms as the RCE and the QHIN mutually agree upon;	The document appears to be inconsistent across these two sections.

Section/ Page Number	Excerpt	Comment
Page 34	Electronic Health Information (EHI): Electronic Protected Health Information, and any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in "electronic media," as defined at 45 CFR § 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.	As in the ONC Notice of Proposed Rule Making (NPRM), there is some confusion in the inclusive definition and scope of Electronic Health Information (EHI). It is critical that this key definition and its relationship to the emerging US Core Data for Interoperability (USCDI) be reconciled.

Section/ Page Number	Excerpt	Comment
Pages 34-35	Health Information Network (HIN): an individual or an entity that satisfies one or both of the following- 1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities; or 2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.	The definition of who could be a HIN or QHIN is vague – unclear on if an IIS or local health department would/could/should qualify? Also unclear how many QHINs ONC envisions operating at one time.

Section/ Page Number	Excerpt	Comment
Page 35	Meaningful Choice: an Individual's choice with respect to the Use or Disclosure of EHI in the context of the applicable Framework Agreement that is: (i) made with advance knowledge as provided by the written privacy summary described in Sections 6.1.5, 7.6, or 8.6, as applicable; (ii) not used as a condition for receiving medical treatment or for discriminatory purposes; and (iii) revocable on a prospective basis if an Individual gives written notice to a QHIN, Participant, or Participant Member.	Despite this definition, it is still unclear how consent is registered via manual or automated data feeds, where consent is maintained, how consent is updated over time, and how consumer/patient consent interacts with reporting mandates and opt-in/opt-out provisions for participation. We recommend more consideration and description on these concepts.
Page 46	2.2.12 Termination of Participation in the Common Agreement. In the event that a QHIN's Common Agreement is terminated due to a material breach of its terms by the QHIN without cure, then the QHIN shall, to the extent required by the Common Agreement, return or destroy all EHI received from, created by, or received by the QHIN that the QHIN still maintains in any form and retain no copies of such EHI except as provided below.	The document outlines requirements upon the termination of a QHIN from the Common Agreement, but there is no mention of the QHIN's relationship to Participants and Individual Users in this case. Are the Participants and Individual Users released from any obligations to the QHIN? If the Participants or Individual Users were required to pay any upfront fees for joining the QHIN, are those fees refunded? Clarification might be helpful.

Section/ Page Number	Excerpt	Comment
Page 48	5.2.1: Reasonable and Non-Discriminatory Fees. A QHIN must use reasonable and non-discriminatory criteria and methods in creating and applying pricing models if it charges any Fees or imposes any other costs or expenses on another QHIN. Nothing in these terms and conditions requires any QHIN to charge or pay any amounts to another QHIN.	This section seems to contain two contradictory statements. The first sentence (A QHIN must use reasonable and non-discriminatory criteria and methods in creating and applying pricing models if it charges any Fees or imposes any other costs or expenses on another QHIN.) implies that a QHIN may impose a fee on another QHIN. Yet the second sentence (Nothing in these terms and conditions requires any QHIN to charge or pay any amounts to another QHIN.) seems to say that no QHIN is obligated to pay such a fee. Please clarify this meaning of this section.
Page 70	The QTF specifies the technical underpinnings for QHIN-to-QHIN exchange and other responsibilities described in the Common Agreement.	Most of the standards (both content and transport) in the document are QHIN to QHIN requirements. TEFCA doesn't appear to be explicit regarding QHIN-to-Participant or Participant-to-Participant Member. It's unclear what the vision is for those exchanges. Are they going to remain using their tried-and-true methods or will they be required to transition to QHIN preferred standards? This would be a considerable lift for IIS (which would require significant funding and time to implement).

Section/ Page Number	Excerpt	Comment
Page 72	A QHIN Query typically involves two major workflows, patient discovery via IHE XCPD and document location/retrieval via IHE XCA.	These sections outline the adoption of IHE profiles but not FHIR or other existing standards. Many existing data exchanges in Public Health use standards other than IHE profiles. If the emphasis is to be on "existing, deployed technical infrastructure" then the adoption of existing HL7 v2, CDA and FHIR standards should be required. As well, given the focus of the ONC and CMS proposed rules on FHIR, adoption of FHIR within TEFCA should be a priority.
Page 82	QHINs MUST be capable of sending and receiving message delivery acknowledgements to and from QHINs and First Degree Entities.	We appreciate that acknowledgment messaging is called out in the actual TEFCA document, but it does not appear in the user guide. We want to ensure that a response to a submitted message is always required.

Section/ Page Number	Excerpt	Comment
Page 82	Specified standards for Message Delivery are included in Table 8… • Responding QHIN(s) MUST be capable of processing XCDR transactions to send documents and associated metadata to the appropriate First Degree Entity(ies) Table 8. Specified and Alternative Standards for Message Delivery: Specified Standard/Profile: IEH XCDR	The standards referenced are IHE XCDR profile to get the data from QHIN A to QHIN B, but it doesn't define the standards on the far left and far right of the swim lane. It does use the words "document and associated metadata", which is concerning. We would prefer this to be message (and not document). Messages = V2. Documents = V3 and/or CDA. At minimum it should include both messages and documents.
Page 82	Initiating QHINs MUST be capable of receiving Message Delivery Solicitations from a First Degree Entity	It is not clear who is responsible for consolidation, deduplication, verification, reconciliation into the new system, etc. Do these activities all happen at the smart phone app (in this example)? There are some critical policy/functional decisions and standards which need to be put in place to both reduce variation and safeguard disclosures when incorrect patient matches are made during queries.
N/A	To help further explain the new TEFCA draft, ONC has provided a User's Guide slide deck, plus a series of 2-page information sheets for different stakeholder groups including state government and public health.	The entire TEFCA document reads well, and the supporting material from ONC is well written and useful.