AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

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Office of the National Coordinator for Health Information Technology

Comments Submitted Electronically to: **exchangeframework@hhs.gov**

RE: Public Comment on Draft Trusted Exchange Framework and US Core Data for Interoperability

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 ***Draft Trusted Exchange Framework*** that was developed in response to the 21st Century Cures Act. These comments are a compilation of the input of our members which include over 75 organizations representing public health Immunization Information Systems (IIS), IIS implementers and vendors, non-profit organizations and partners. Immunization Information Systems interface with a broad range of stakeholders, including providers, pharmacists, schools, child care facilities, health plans and payers, among others. 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.

We appreciate the opportunity to provide comment 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.

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 the CDC IIS Annual Report.[1] 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

[1] https://www.cdc.gov/mmwr/volumes/66/wr/mm6643a4.htm

well.[2] Meaningful use and the adoption of Certified Electronic Health Record Technology (CEHRT) by the EHR (Electronic Health Record) community have helped to accelerate the pace of interoperability across IIS and EHRs.

AIRA's general comments on the Draft Trusted Exchange Framework and the Draft US Core Data for Interoperability (USCDI) are presented below, and more detailed comments are presented on the following pages, called out by page number and section where appropriate.

Comments in Support:

We applaud the vision of an improved health system articulated in the Framework:

A system where an individual's health information is not limited to what is stored in electronic health records (EHRs), but includes information from many different sources (including technologies that individuals use every day) and provides a longitudinal picture of their health.

It is relevant to note that most IIS provide that longitudinal view today, consolidating immunizations for individuals across their lifespan. This complete birth-to-death record fuels accurate clinical decision support at the point of care, as well as aggregate analysis for population health.

The first goal articulated for TEFCA, to build on and extend existing work throughout the industry, is an excellent place to start. Conceptualizing TEFCA as a Framework to augment, not replace, current exchanges is extremely useful.

We are encouraged to see public health called out as a permitted purpose in Part B, Section 1. Public Health in general, and IIS specifically, provide essential and cost-effective value, both to the general population, in protecting against communicable disease, but also to individual providers, empowering them with the most accurate and complete immunization information available. We also applaud the prohibition on QHINs charging money for responding to queries/pulls for Public Health.

The introduction of a single "on-ramp" that connects one network to multiple networks could bring significant efficiencies to Public Health, through eliminating the costs of connecting to multiple networks, eliminating costly point-to-point agreements, reducing individual system interfaces, and allowing the use of provider identity-proofing and authentication provided by others.

Across the immunizing community, we can envision this Framework supporting a number of use cases, including facilitating interjurisdictional exchange of data, speeding query response of consolidated records and forecasts, and improving data completeness and accuracy through broadcast and directed queries. It is also encouraging that federal

[2] http://www.immregistries.org/initiatives/measurement-and-improvement-initiative

agencies could potentially require use of TEFCA as a method to advance implementation within and beyond Public Health.

The principles articulated in Part A of the Framework of Standardization, Transparency, Cooperation and Non-Discrimination, Privacy, Security and Safety, Access, and Data-driven Accountability are all very much in line with the values of Public Health.

Comments of Concern/Recommendations

However, it is important to note that very few public health data exchange transactions are supported by the architecture described in these documents. Most immunization reporting is done via unsolicited (or "push") HL7 v2 messages. HL7 v2 is called out in ONC and CMS regulations as a required messaging standard for EHR Certification for immunization messaging. Submission and queries to public health registries are usually executed with a known end-point (*i.e.,* the registry in the clinician's jurisdiction) using HL7 v2 messaging. **To improve consistent adoption, we would encourage HL7 V2 to be added to the "floor" of the Trusted Exchange Framework.**

To fully populate IIS, the majority of data is "pushed" from provider offices, hospitals, and health systems, occasionally in batch form but increasingly through real-time messaging. Although the EHR and IIS community are broadly embracing query to pull in the consolidated record and forecast at the point of care, this does not replace the need for data to be pushed to an IIS to ensure the longitudinal immunization record is complete. The current use of "DIRECT" messaging does not meet the real-time needs of the immunization community, nor does it establish any permitted purposes or formal trust network. Given that much of immunization data is messaged via "push" or notification messaging, **we would encourage a Use Case for "push" data submission or notifications, using HL7 V2 standards, be added to the Framework.**

Although the "single onramp" is an efficient and appealing concept, we do have questions about how data quality testing and onboarding would take place for individual IIS. The IIS community has vast experience with testing to ensure the consistency of both format and content of incoming data. This testing process is crucial to ensure data meets standards for acceptance and future data use purposes. **We ask that ONC develop a comprehensive process for testing and onboarding across participants in the final Framework to ensure the quality of data exchanged.**

Allowing the use of provider directories, albeit federated, may improve the efficiency of data exchange. However, more should be documented regarding provider directories to ensure that the hierarchies of providers, provider groups, QHINs and others (e.g., associations between providers, clinics, health systems, EHR hubs, Regional HIEs, etc.) are consistently organized to meet public health needs. **As part of the establishment of provider directories, we would encourage a thorough landscape analysis of current data exchange needs throughout public health to ensure established levels of exchange are not disrupted.**

The Framework also does not address in depth the challenges of inconsistent state, local and tribal patient consent and data sharing laws that are often an obstacle to cross-jurisdiction interoperability. It is not clear how these consent issues might be overcome with the current framework. **We would welcome more clear and detailed explanations of how jurisdiction-specific consent and data sharing laws and rules will be addressed by the Framework to support interoperability.**

With respect to immunization data, perpetuating consent (to Master Patient Indexes, Record Locator Services, etc.) will likely be a significant issue. Immunization data (and most public health data) can only be used for the purpose and by the entities/individuals who have a right to access it under very individualistic state requirements. That really means that the QHINs should have a way to identify the type of person/entity requesting the data and ensure that their use of the data is appropriate. **We would encourage ONC to expand on how this issue of data ownership and permitted uses will be addressed in the final Framework.**

We are concerned that the requirement for a Qualified Health Information Network (QHIN) to implement standards within twelve months of their publication may be unrealistic. The standards development process is ongoing, yet it takes longer for a set of systems fulfilling a particular use case to implement a particular version of a standard consistently and pervasively. As a corollary example, many stages of Meaningful Use were delayed due to slow provider and EHR implementation. Organizations – including public health agencies but also EHR systems and end-user providers – can be slow to migrate to newer standards. Even for C-CDA and FHIR standards, new (and sometimes conflicting) profiles are developed continuously and it may not be clear which one is appropriate to use. **We would encourage ONC to consider extending the time period for implementation of new standards, as 12 months may be unrealistic in practice.**

We also have some concerns regarding the Recognized Coordinating Entity, or RCE. Government has specific responsibilities for ensuring public health. In standing up the RCE with a cooperative agreement, ONC is delegating some governmental responsibilities to a private sector RCE. **Public health needs to be represented in developing the governance and in managing the RCE.**

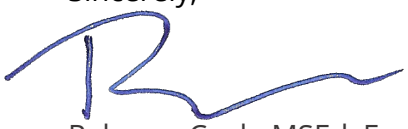
The Draft US Core Data for Interoperability (USCDI) introduces some additional uncertainly. It is not clear how an ever-expanding set of core data may be met moving forward, given the differences in exchange today. It is also unclear how the HIPAA notion of "minimum necessary" applies to the requirement for transmitting a pre-determined core set of data, as the C-CDA would contain much more data than needed for immunization use. Furthermore, the IIS community has learned from experience that highly constrained implementation guides and testing are also required to ensure smooth interoperability. The Immunization Community uses the CDC-Endorsed Data Elements as a reference point for data for interoperability, and more work is underway within AIRA to further define the characteristics of those elements. This may yield helpful lessons for ONC to leverage in further developing the USCDI, and we would welcome the opportunity to share this work.

We ask that these issues related to core data elements, alternatives to the C-CDA, implementation guides and testing be further explored, articulated and documented in the final Framework.

Finally, we would encourage ONC to revisit the core responsibilities of Public Health in considering our critical role within TEFCA. The role of Public Health referred to in TEFCA is as follows: "*We seek a system where public health agencies and researchers can rapidly learn, develop, and deliver cutting edge treatments by having secure, appropriate access to Electronic Health Information."* However, Public Health's roles and responsibilities do not focus on cutting edge treatments as much as promoting and protecting the health of people and communities.[3] **Data and interoperability are essential tools to ensure Public Health can meet this charge, and we look forward to partnering with ONC to help craft a meaningful role for Public Health in TEFCA.**

The following table includes further detailed comments by section. 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. Please contact me with any questions at coyler@immregistries.org.

Sincerely,



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

[3] https://www.apha.org/what-is-public-health

Comments on the Draft Trusted Exchange Framework

Section/ Page Number	Excerpt	Comment
p. 6	… establishing a single "on ramp" to Electronic Health Information that works regardless of one's chosen network is feasible and achievable.	The use of the term "on ramp" is somewhat unclear in the document itself. This has been clarified on ONC informational calls as a conceptual metaphor, rather than an actual process. We ask that the document reflect these clarifications.
p. 7, second paragraph	…the proposed Trusted Exchange Framework supports four important outcomes: 1) providers can access health information about their patients, regardless of where the patient received care; 2) patients can access their health information electronically without any special effort; 3) providers and payer organizations accountable for managing benefits and the health of populations can receive necessary and appropriate information on a group of individuals without having to access one record at a time (Population Level Data),17 which would allow them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives; and 4) the health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation to make health information more accessible and to improve electronic health record (EHR) usability.	While the four key outcomes listed do not exclude public health, they do not explicitly mention public health or public health goals either. We would like to see public health called out alongside providers and payer organizations under outcome #3 as an entity accountable for managing the health of populations, and ideally, also alongside providers under outcome #1 as an entity needing access to health information about patients/individuals, regardless of where the patient or individual received care.

Section/ Page Number	Excerpt	Comment
p. 14	Adhere to standards for Electronic Health Information and interoperability that have been adopted by the Secretary of the U.S. Department of Health & Human Services (HHS) or identified by ONC in the Interoperability Standards Advisory (ISA).	As written, principal 1.A indicates support for things in the ISA or 2015 certification - which includes the HL7 V2 IG, the standard broadly implemented across the EHR and IIS/Immunization community. It's not clear if this would apply just to inter-QHIN exchanges (where other alternatives like C-CDA or FHIR might be available for immunization data) or if it also applies to intra-QHIN exchanges were data is collected from individual sources (EHRs or IISs) which may be the bigger impact to EHR/IIS. The text explaining this principle may not be fully sensitive to public health's needs or perspective, as it is focused more heavily on CEHRT.
p. 18, Sub-principle 3A	Qualified HINs… should not use contract provisions or proprietary technology implementations to unduly limit connectivity with other Qualified HINs, such as…	While we agree that information blocking is a bad thing, this section may imply that HINs need to invest *equally* in strategies that support interoperability within outside networks as they do within their "preferred networks." Is this the intent of this section?
p. 20	Patient withdrawal from participation in a Qualified HIN	It is important to note that in some jurisdictions, certain types of patients *cannot* opt-out of inclusion in certain public health registries. If the Qualified HIN is a party to the transaction then this policy would not apply. This overlaps with earlier comments regarding the capture and perpetuation of consent throughout the exchange network.

Section/ Page Number	Excerpt	Comment
p. 21	Supporting these types of use cases necessitates the ability to exchange multiple patient records at one time (i.e. population level or “bulk transfer”), rather than potentially performing hundreds of data pulls or pushes for a panel of patients. Qualified HINs should provide the ability for participants to both pull and push population level records in a single transaction.	The IIS community does not have a standard for this today. Historically this hasn't been needed, but it's something IIS could support with a proper standard and desire.
p. 25	Directed Query	This term may be confused with the Direct Protocol which clearly is not what is intended. Perhaps “Targeted Query” would avoid this confusion.
p. 28	Qualified HIN	This definition states that, “none of the exchanges of EHI by or on behalf of the Qualified HIN include the Qualified HIN itself….” This may be problematic for some HINs such as those that support large vertical networks (like Kaiser).

Section/ Page Number	Excerpt	Comment
p. 30, 2.4	Each Qualified HIN shall implement the APIs necessary to perform its obligations hereunder within twelve (12) months of the date of the API Implementation Guide being formally adopted by HL7 on its public website and recognized by ONC on its public website.	The requirement that a Qualified HIN implement APIs embedded in standards within 12 months of their publication seems somewhat unrealistic. The standards development process is ongoing, yet it takes longer for a set of systems fulfilling a particular use case to implement a particular version of a standard consistently and pervasively. For example, though the Immunization Information System community is still working to implement HL7 v2.5.1 messaging, HL7 has already balloted a v2.9 message. Organizations – including public health agencies – are unprepared to migrate to newer standards just because HL7 has published them. Even for C-CDA and FHIR standards, new (and sometimes conflicting) profiles are developed continuously and it may not be clear which one is appropriate to use.
p. 30, 2.3	Mandatory Updating of the USCDI. Each Qualified HIN shall update its data format and/or API to include new data classes (including, without limitation, specified clinical data fields) added to the USCDI within a reasonable time (not less than twelve (12) months) after the date of the data classes being officially added to the USCDI.	Should it be "not more than" rather than "not less than"?

Section/ Page Number	Excerpt	Comment
p. 31, 2.7	Except as otherwise expressly provided herein, whenever this Agreement references any standard, implementation specification, or certification criteria to which a Qualified HIN or Participant must comply, the Qualified HIN or Participant shall not be required to comply with any updates to such standards, implementation specifications or certification criteria until twelve (12) months after such standard has been formally adopted by HHS or other applicable authority.	This timeline would be extremely challenging for public health given funding cycles and contracts.
p. 31, 3.1.1	The Broker shall send and receive all of the EHI in the data classes included in the then Current USCDI when and to the extent such EHI is requested and electronically available within or through the Qualified HIN's Health Information Network.	It is unclear how the HIPAA notion of "minimum necessary" applies to the requirement for transmitting USCDI.
p. 31, 3.1.1	The Broker shall send and receive all of the EHI in the data classes included in the then Current USCDI when and to the extent such EHI is requested and electronically available within or through the Qualified HIN's Health Information Network.	Some of the data in the USCDI is not relevant for IIS (e.g., vital signs, clinical notes). As the list grows in the future years, this list of items an IIS is not interested in or cannot see will be larger.

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p. 31, 3.1.3	As more fully described in the following provisions of this Section 3, the Qualified HIN's Broker shall adhere to standards and implementation specifications for electronic data and interoperability that are outlined in 45 C.F.R. Part 170, Subpart B as applicable and referenced in the 2015 Edition (or any then applicable standards and implementation specifications adopted in the future by HHS) for the uses to which those standards and implementation specifications are applied.	Although immunization is noted here (1.4, 1.5, and addendum), the SOAP/WS and the CDC WSDL, as the transport method for IIS data, is not. We strongly recommend the inclusion of SOAP/WS and the CDC WSDL.
p. 32, 3.1.5	Within twelve (12) months after the FHIR standard with respect to Population Level Query/Pulls has been formally approved by HL7, each Qualified HIN shall cause its Broker to be able to initiate and respond to all Query/Pulls for as many individuals as may be requested by another Qualified HIN in a single Query/Pull.	If this is talking about base resources, a FHIR Maturity Level or "normative status" should be referenced. "Normative status" probably also applies to profiles/IGs. Is HL7 creating a U.S. Profile for this, or is this referring to the base FHIR Resources, which might be quite loose and result in varied implementations.
p. 32, 3.1.8	Initiating Queries. The Qualified HIN shall cause its Broker to perform the following functions when initiating any Query/Pull:	This section and other sections presume a very specific set of technologies which are not being used dominantly today in the US. Is it ONC's intention that *all* inter-organizational interoperability move to use these technologies?

Section/ Page Number	Excerpt	Comment
p. 33	The responding Qualified HIN's Broker may use any internally defined interactions (such as individual matching, provider identity, data transmission) to retrieve all of the EHI in the data classes included in the then Current USCDI from its Participants as long as it responds to the initiating Qualified HIN's Broker in accordance with the other requirements of this Section 3. Additionally, regardless of the format and any problems that may arise from the format in which the Participant entered the EHI or makes it available for a response, the responding Broker is responsible for returning all of the EHI in the data classes included in the then Current USCDI, when and to the extent that such EHI is available and has been requested and the response is in compliance with Applicable Law;	This section opens the door for any mechanism of communication within a QHIN which is likely where the most Public Health agencies fit as a participant. To minimize change from current exchange standards, TEFCA should at least state a preference for 2015 certification methods be used within a QHIN
p. 33	If more than one Participant internal to the Qualified HIN's Health Information Network has the desired EHI, the responding Broker shall consolidate the results from the multiple Participants into one response to the initiating Broker.	The meaning of "consolidate" is ambiguous. For example, if multiple Participants contain a patient's immunization history, does the Broker have to reconcile the immunization events from both participants into a single list with duplicate entries removed, or do they simply have to include data from both participants in the response? Please expand on the Broker responsibilities in terms of consolidating overlapping data from multiple Participants.

Section/ Page Number	Excerpt	Comment
p. 36, 5.3.2	Notwithstanding anything to the contrary set forth in the Common Agreement or elsewhere, a responding Qualified HIN may not charge any amount for responding to Queries/Pulls for the Permitted Purposes of Individual Access, Public Health or Benefits Determination.	We applaud the prohibition on a Qualified HIN charging money for responding to queries related to public health.
p. 36, 6.1.2	Once ePHI is shared with another Qualified HIN, the receiving Qualified HIN may exchange, retain, Use and Disclose such ePHI only to perform functions in connection with the Permitted Purposes in accordance with the Common Agreement and the Qualified HIN's Participant Agreements, or as otherwise permitted by Applicable Law.	This issue of re-disclosure of data that was originally submitted to public health and is then returned by public health in response to a query is an important one. We applaud the inclusion of this in the Common Agreement, though additional review and discussion may be warranted.
p. 37, 6.1.6	Each Qualified HIN shall require its Participants to provide the Qualified HIN with a copy of each consent of a Qualified HIN's consenting individual and the Qualified HIN shall maintain copies…	The section on providing a copy of consent is insufficient. For example, an electronic copy conveyed in a PDF document is of limited use and will not help to build systems that can more transparently *use* consent directives to control interoperability.
p. 40, 6.2.7	SOAP-based Security. Each Qualified HIN's SOAP-based servers shall conform to the connection authentication requirements as specified in the IHE ATNA Integration Profile for Transport Authentication Security.	The IIS transport standard of SOAP/WS and the CDC WSDL do not meet these more complex IHE standards. We request that the standard be loosened to include SOAP/WS and the CDC WSDL, the transport standard for IIS.

Section/ Page Number	Excerpt	Comment
p. 42, 6.2.8(ii)	The certificate authority's certificate shall be issued by a mutually trusted certificate authority;	It is not clear what is meant by a "mutually trusted certificate authority." Digital certificates must be trusted by *all* participants in health information exchange. Is this requirement stipulated that a *participant's* digital certificate must be trusted only by the Qualified HIN to which the participant has a connection?