



October 1, 2018

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue SW, Suite 729-D
Washington, DC 20201

Submitted Electronically

RE: Public Comment on ONC 2018 Interoperability Standards Advisory

Dear Office of the National Coordinator for Health IT:

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit updated comments on ONC's **2018 Interoperability Standards Advisory**. These comments are a compilation of the collective input of our members. 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.

AIRA's comments are presented on the following pages, called out by section within the Standards Advisory. 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 coordinate the adoption of standards specifications across agencies, and we look forward to supporting our members and partners in adopting selected standards.

Sincerely,

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



Comments on the ONC 2018 Interoperability Standards Advisory

Section and/or Section Number	Excerpt	Comment
Scope	" Starting with the 2017 ISA, the ISA's focus expanded to more explicitly include public health and health research interoperability."	We applaud the increasingly explicit focus on public health as an important part of Health IT.
Representing Immunizations – Administered	Standard: RxNorm	<p>Adoption of RxNorm is listed at "Feedback Requested". The AIRA/IIS community has not adopted RxNorm and it is not planned for adoption either in the near or long term given the movement to NDC found in regulations.</p> <p>A second consideration for RxNorm is in the listed limitations. This comment is about CPT, but we believe it can apply to RxNorm as well. The statement about CPT "CPT is an acceptable alternative code set for local use, but may have limitations for interoperability across systems." is true about RxNorm as well. AIRA recommends updating the statement to read "CPT and RxNorm are acceptable alternative code sets for local use, but are not the code sets federally required for exchange with immunization registries."</p> <p>We are also curious about why RxNorm is listed only in the Applicable Value Set(s) and Starter Set(s) section and not in the primary table for historical vaccines, but only in the primary table but not the Value Set(s) and Starter Set(s) section for administered vaccines.</p>





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Representing Immunizations – Administered	Standard: NDC “There is a potential issue with use of the National Drug Code regarding which code to use when there are multiple active ingredients in a single package or multiple separate ingredients that need to be mixed together.”	We fully support the increased focus on NDC as a code set for submitting administered vaccinations. CDC has published guidance on NDC Unit of Use and Unit of Sale; it can be found at: https://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/downloads/guidance-documenting-ndc.pdf
Representing Immunizations – Historical	Standard/Implementation Specification: CVX, MVX	We support the focus on CVX and MVX as the primary code sets. We also support RxNorm being deemphasized. The AIRA/IIS community has not adopted RxNorm and it is not planned for adoption either in the near or long term.





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Representing Immunizations – Historical	Standard: MVX	The limitation regarding MVX reads “While the information is very helpful, MVX is fairly rare to have for historical vaccinations and is unrealistic to have providers collect.” The first half of the statement is likely true, but ignoring MVX information if it is present devalues the historical clinical record. If MVX is available it should be collected. Since under Federal law recording the vaccine manufacturer in the medical record is required for vaccines covered under the National Childhood Vaccine Injury Act, this information should be historically available in many cases. The standards should encourage the transfer of this information from their primary source to a secondary source – either a new Practice or from paper to electronic format AIRA suggests updating the statement to read “MVX is fairly rare to have for historical vaccines; however if a provider has the information it should be captured and messaged as part of the historical vaccination record.”



Section and/or Section Number	Excerpt	Comment
Exchanging Immunization Data with Immunization Registries	<p>“Applicable Value Set(s) and Starter Set(s)”</p> <ul style="list-style-type: none"> ▪ Secure Communication – create a secure channel for client-to-server and server-to-server communication. ▪ Secure Message Router – securely route and enforce policy on inbound and outbound messages without interruption of delivery. ▪ Authentication Enforcer – centralized authentication processes. ▪ Authorization Enforcer – specifies access control policies. ▪ Credential Tokenizer – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). ▪ Assertion Builder – define processing logic for identity, authorization and attribute statements. ▪ User Role – identifies the role asserted by the individual initiating the transaction. ▪ Purpose of Use - Identifies the purpose for the transaction 	<p>It is not clear to us what these Value Set(s) and Starter Set(s) are meant to represent.</p>



Section and/or Section Number	Excerpt	Comment
Exchanging Immunization Data with Immunization Registries	HL7 2.5.1 Release 1.4, Test Tool Availability	This link to the Test Tool Availability for Release 1.4 is broken. We also question whether testing should be included for Release 1.4, since all new implementations should be focused on Release 1.5.
Exchanging Immunization Data with Immunization Registries	HL7 2.5.1 Release 1.5	We believe the adoption level may be higher than 3/5 for Release 1.5; consider 4/5.
Transport for Immunization Submission and Query/Response	CDC-EHR-IIS Interoperability Enhancement Project Transport Layer Protocol Recommendation Formal Specification, Web Site Disclaimers Version 1.2	We believe the adoption level may be higher than 3/5 for the transport standard; consider 4/5.

