AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

October 30, 2015

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 2016 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 comments on ONC's ***2016 Interoperability Standards Advisory: Best Available Standards and Implementation Specifications***. As a member organization for over 60 Public Health organizations, 11 businesses and sponsors, and 26 individuals representing Immunization Information System (IIS) programs and partners, these comments represent a broad perspective on federal actions that impact immunization programs across the country, and we are particularly interested in informing standards specifications.

AIRA's comments are presented on the following pages, organized by page number and section within the Standards Advisory. Please contact Rebecca Coyle, AIRA's Executive Director, with any questions: coyler@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 MSEd, Executive Director
American Immunization Registry Association (AIRA)

AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

Comments on the ONC Interoperability Standards Advisory

By: AIRA

Section/ Page Number	***Excerpt***	***Comment***
Section 1-D: Race and Ethnicity Page 10	Standard/Implementation Specification: OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997	It is not clear if this standard would require IIS to have the capability to exchange all 900+ codes or if it is sufficient to use the aggregated OMB standard values for interoperability with electronic health record systems (EHR-S). AIRA believes that the maintenance of 900+ codes by both IIS and EHR would create unnecessary burden with limited return on investment, so we would support the use of the aggregated OMB codes. To clarify this point, we would ask that systems such as IIS be called out and identified in the bullet point below under Limitations, Dependencies and Preconditions for Consideration that states: The HIT Standards Committee noted that the high-level race/ethnicity categories in the OMB Standard may be suitable for statistical or epidemiologic purposes but may not be adequate in the pursuit of precision medicine and enhancing therapy or clinical decisions.
Section 1-H: Interoperability Need: Representing Immunizations – administered	Standard/Implementation Specification: HL7 Standard Code Set CVX—Clinical Vaccines Administered	If CVX codes are called out as a standard code set for administered immunizations, MVX codes should be called out as well, as they were above for historical immunizations. Although it is important to receive MVX paired with a CVX for both historical and administered immunizations, it is especially important for administered immunizations to allow for derivation of a specific trade name.
Section 1-H: Interoperability Need: Representing Immunizations – administered	Standard/Implementation Specification: National Drug Code **Limitations, Dependencies, and Preconditions for Consideration:** According to the HIT Standards Committee, National Drug (NDC) codes may provide value to stakeholders for inventory management, packaging, lot numbers,	Although AIRA has advocated and continues to advocate for CVX/MVX as the preferred code sets for reporting administered immunizations, we recognize that NDC codes are increasingly being used across the health care marketplace, and are an adequate (albeit burdensome) code set for documenting and messaging administered immunizations. In addition, they have been called out as the preferred code set in the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification

AIRA AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

	etc., but do not contain sufficient information to be used for documenting an administered immunization across organizational boundaries.	Program Modifications rule: "For the purposes of administered vaccines, when an immunization is reported at the time it is administered and the actual product is known, the NDC code must be sent." As such, we believe the bullet point under limitations: "According to the HIT Standards Committee, National Drug (NDC) codes may provide value to stakeholders for inventory management, packaging, lot numbers, etc., but do not contain sufficient information to be used for documenting an administered immunization across organizational boundaries." is inaccurate and confusing. However, we also do not believe that current adoption is at the highest level (81%-100%), and we recommend that the adoption level be lowered to more realistically recognize the significant adoption of this code set that is yet to come across the EHR and IIS community. Although it is challenging to quantify, considering that stage 1 and 2 of Meaningful Use required use of CVX for administered immunizations, AIRA believes that adoption of NDCs is at the lower end of the adoption scale for both EHRs and IIS.
Section I-K: Medications	Standard/Implementation Specification: RxNorm	AIRA would support adding a bullet under Limitations, Dependencies, and Preconditions for Consideration that vaccines are not considered medications.
Section II-K: Public Health Reporting	Standard/Implementation Specification: Reporting administered immunizations to immunization registry: *HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5*	AIRA recommends that implementation maturity for the Release 1.5 Guide be listed as Production rather than Pilot, and that Adoption Level be represented higher to reflect the true level of adoption across Public Health. Given that adoption of the Release 1.4 guide is listed at 81%-100%, the Release 1.5 guide should more realistically be listed at 61%-80% adoption. In addition, with the publication of the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications rule, this should be considered Regulated (excerpt from the rule: " We, therefore, have adopted HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 1, 2014) and HL7 Version 2.5.1: Implementation Guide for Immunization Messaging,

AIRA AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

		Release 1.5, Addendum (July 2015) for the transmission to immunization requirement.")
Section III-A: An unsolicited "push" of clinical health information to a known destination	Interoperability Need: An unsolicited "push" of clinical health information to a known destination between individuals	AIRA recommends adding the immunization specification for SOAP/Web Services and the CDC WSDL as the standard interface to this section as the recognized transport specification for EHR-IIS messaging. See http://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/services.html and http://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/wsdl.html.
Section III-F: Query	Interoperability Need: Data element based query for clinical health information	AIRA recommends adding HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 2014) and Release 1.5 Addendum (July 2015) to provide a reference for QBP/RSP query for EHR-IIS interoperability.
Section IV: Questions	4.1: Please provide feedback on whether revision from "purpose" to "interoperability need" provides the additional requested context and suggestions for how to continue to improve this portion.	AIRA believes that "interoperability needs" is a more clear way to convey the context of standards than "purpose."
Section IV: Questions	4.2: For each standard and implementation specification there are six assessment characteristics. Please review the information provided in each of these tables and check for accuracy. Also, please help complete any missing or "unknown" information.	See comments above regarding AIRA's recommendations on modifying assessment characteristics.
Section IV: Questions	4.3: Please review examples found in Sections III-A and III-F and provide feedback as to the usefulness of this approach and any information you know for a specific interoperability need.	No comment.

AIRA AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

Section IV: Questions	4.4: For each interoperability need, there is a table beneath the standards and implementation specifications that includes limitations, dependencies, and preconditions. This draft only includes select examples for how this section would be populated in the future. Please review populated sections and provide feedback as to the usefulness of this approach and any specific information you know for a specific interoperability need.	Interoperability is essential to public health reporting and leveraging the vast amount of information collected at the point of care to improve population outcomes. AIRA, like many of our partner organizations, promotes the use of standards in health information, and, however, recognizes that variations in state regulations and need may necessitate state-specific implementation specifications. Providing the condition to confirm with public health jurisdictions under the "limitations, dependencies, and preconditions" heading for public health reporting is a necessary footnote to help remind implementers of that need. It is unclear how the adoption level metric is calculated. More explanation on how this measure is created with an explanation on how frequently it is updated will be necessary to prove value in iterative releases of the standards advisory. This will help to identify a shift in standard adoption as well as indicate when a standard or implementation specification has reached wide-spread adoption.