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March 17, 2016

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 in preparation for 2017 version

Dear Office of the National Coordinator for Health IT:

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit additional comments on ONC's **2016 Interoperability Standards Advisory: Best Available Standards and Implementation Specifications** in preparation for a 2017 release. These comments represent the collective input of our member organization of over 60 Public Health organizations, 11 businesses and sponsors, and 26 individuals representing Immunization Information System (IIS) programs and partners.

AIRA's comments are presented on the following page, called out 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,

A handwritten signature in blue ink, appearing to be "Rebecca Coyle", is located below the "Sincerely," text. The signature is fluid and cursive.

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

Comments on the ONC 2016 Interoperability Standards Advisory

By: AIRA

Section/ Page Number	Excerpt	Comment
Section I-H: Interoperability Need: Representing Immunizations – administered	Standard/ Implementation Specification: <u>HL7 Standard Code Set CVX—Clinical Vaccines Administered</u>	<p>The Standards Advisory’s treatment of historical vs. administered immunizations is confusing as currently written. 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 helpful to receive MVX paired with a CVX for historical immunizations when possible, it is often not available for historical immunizations. However, it is critically important to receive both CVX and MVX for administered immunizations to allow for derivation of a specific trade name.</p> <p>With the preferred code set of National Drug Codes (NDC) now called out in the 2015 Edition Health Information Technology (Health IT) Certification Criteria, this section may need to be modified further (see subsequent comment).</p> <p>In addition, although MVX was not called out in the final ONC Certified EHR Technology rules, it should always accompany CVX when messaging an administered dose (this is not necessary when reporting NDC, as the manufacturer is embedded in the NDC code itself). AIRA requests that this point be clarified in the Limitations, Dependencies and Preconditions for Consideration section.</p>
Section I-H: Interoperability Need: Representing Immunizations – administered	Standard/ Implementation Specification: <u>National Drug Code</u> 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, etc., but do not contain sufficient information to be used for documenting an administered immunization across organizational boundaries.	NDC codes are increasingly being used across the health care marketplace, and are an appropriate code set for documenting and messaging administered immunizations. 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 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 because they <u>can</u> be used across organizational boundaries, provided all parties are prepared to send and receive NDC codes. For these reasons, AIRA asks that this bullet point under limitations be removed or reworded.