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April 29, 2015

Dr. Karen DeSalvo  
Office of the National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services

RE: ONC 2015 Interoperability Standards Advisory

Dear Dr. DeSalvo,

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on ONC's ***2015 Interoperability Standards Advisory: Best Available Standards and Implementation Specifications***. As a member organization for 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](mailto: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.

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

## Comments on the ONC Interoperability Standards Advisory

By: AIRA

Section/ Page Number	Excerpt	Comment
Section I: Best Available Vocabulary/ Code Set/ Terminology Standards and Implementation Specifications Page 7	Immunizations – Historical  <b>[See Question #5-10]</b> •[R] HL7 Standard Code Set CVX— ClinicalVaccines Administered  •MVX (Manufacturing Vaccine Formulation)	<p>AIRA supports the inclusion of CVX as the primary method for reporting historical doses, and MVX as an additional data element when it is available, noting that MVX is not always known for a historical dose. When it is known, however, it provides helpful additional data to infer the brand of vaccine administered.</p> <p>AIRA believes it is important to define the concepts of “administered” and “historical”, however. Per AIRA’s Modeling of Immunization Registry Operations Workgroup (MIROW) Manual, Chapter 7 on Data Quality, administered and historical are differentiated as follows:</p> <p>“Administered” value for the Administered/Historical Indicator points out that the Immunization Information System Authorized Organization (IIS-AO) submits its own Vaccination Event, i.e., attests that it conducted the Vaccination Event (“I am the Vaccinator IIS-AO”).</p> <ul style="list-style-type: none"> <li>• In this case, expanded set of data items for a Vaccination Event Submission would be expected (this is the Best Practice -- see BR105R1, chapter 5).</li> <li>• In some cases, IIS-AO submits its own Vaccination Event (“administered”), but does not have all expected information for the expanded set of data items. Following are three situations when a reduced set of data items for an “administered” Vaccination Event submission may be allowed (see BR105R2, chapter.             <ul style="list-style-type: none"> <li>○ Legacy immunizations. Example is an IIS-AO that begins reporting to (comes onboard) IIS and wants to submit information about Vaccination Events it conducted some time ago, before entering into an agreement with IIS.</li> <li>○ Limited EHR capacity. In some cases, EHR that IIS-AO uses does not</li> </ul> </li> </ul>



		<p>support expanded set of data elements, so IIS-AO is not able to send them. IIS still wants the data and cannot mandate upgrade to EHR.</p> <ul style="list-style-type: none"> <li>▪ This situation would be for a limited time period, as established by the IIS.</li> </ul> <ul style="list-style-type: none"> <li>○ Birth Doses. HepB and other hospital birth doses may not have all required data elements available.</li> <li>○ Notes: <ul style="list-style-type: none"> <li>▪ Rules for accepting or rejecting "Administered" Vaccination Event Submissions with less than the expanded data set should be the same for Electronic Data Exchange and Direct User Interface submissions.</li> <li>▪ When reduced set of data items is reported for the "Administered" Vaccination Event, an error message should always be sent or displayed in the UI. Also, other methods of communicating data quality problems should be employed, i.e., monthly reports.</li> </ul> </li> </ul> <p>"Historical" value for the Administered/Historical Indicator points out that the IIS-AO originates a Vaccination Event Submission for a Vaccination Event that was administered (and therefore, owned) by some other entity ("I am NOT Vaccinator IIS-AO; I am just Recorder IIS-AO").</p> <ul style="list-style-type: none"> <li>• In this case, a reduced set of data items for a Vaccination Event Submission would be expected.</li> </ul>
Section I: Best Available Vocabulary/ Code Set/ Terminology Standards and	Immunizations – Administered  <b>[See Question #5-11]</b> National Drug Codes (NDC)	It is important to recognize that NDC codes change and are added more frequently than CVX and MVX codes so relying on those as the sole source for vaccine administration records would require changes by some IIS, and may also necessitate additional maintenance to the IIS as the codes are changed and updated. There are also continued challenges with



<p>Implementation Specifications Page 7</p>		<p>dual NDC codes on external packaging and on unit of use, so additional mapping functionality would be essential. Finally, NDC is not a commonly leveraged data element currently in EHRs. Using NDC would require a significant development effort for the EHR community, as well as potential unnecessary burden to maintain and update the NDC codeset at each provider practice.</p> <p>It is also unclear whether NDC codes would be appropriate for use with bidirectional (patient history/forecast query) message exchanges. The Standards Advisory does not address this use case directly, but recognizing that the use of CVX/MVX is a current practice in IIS-EHR bidirectional exchanges, primary use of NDC over CVX/MVX brings up significant concerns.</p> <p>Finally, see comments above regarding the importance of common definitions regarding differentiating historical and administered immunizations.</p> <p>For these reasons, AIRA would support CVX and MVX as the preferred codesets for administered immunizations, while NDC continues to be used in 2D barcoding and some inventory decrementing. We would also like to collaborate in evaluating the benefits and costs of transitioning to NDC as a potential replacement codeset for administered immunizations in the future.</p>
<p>Section III: Best Available Transport Standards and Implementation Specifications Page 10</p>	<p><b>Data sharing through Service Oriented Architecture (SOA) - that enables two systems to interoperate together – Standards:</b></p> <ol style="list-style-type: none"> <li>1) Hypertext Transfer Protocol (HTTP) 1.1, RFC 723X (to support RESTful transport approaches)</li> <li>2) Simple Object Access Protocol (SOAP) 1.2</li> <li>3) For security, Transport Layer Security (TLS)</li> </ol>	<p>Although there may be benefits to multiple transport standards, AIRA would like to recognize that the IIS community has selected SOAP as our chosen standard, and we believe that selecting a preferred standard may accelerate interoperability efforts. For more information, see <a href="http://www.cdc.gov/vaccines/programs/iis/technical-guidance/SOAP/services.html">http://www.cdc.gov/vaccines/programs/iis/technical-guidance/SOAP/services.html</a> and/or <a href="http://www.cdc.gov/vaccines/programs/iis/interop-proj/downloads/SOAP-br.pdf">http://www.cdc.gov/vaccines/programs/iis/interop-proj/downloads/SOAP-br.pdf</a></p>



	Protocol Version 1.2, RFC 5246	
Section IV: Annual Process to Update the Interoperability Standards Advisory	ONC intends to implement the following timeline and process to update the Interoperability Standards Advisory for subsequent years. The process for the open draft 2015 Advisory will roughly follow this same process despite its later publication date in 2015.	<p>Although AIRA understands that the Standards Advisory itself will be updated annually, and not necessarily the standards themselves, there is some concern that an annual update may be too frequent or may create room for too much evolution of standards. The HIE community struggles to adopt and implement standards in a timely way as it is. AIRA would encourage consideration of a date range for a given standard, for example, proposing a standard in 2016 for use through 2020, with reconsideration for modification as the retirement or sunset date for a given standard is approached.</p> <p>This document should acknowledge the fact that while standardized vocabularies and code sets (LOINC, SNOMED, CVX, etc.) represent an excellent opportunity to advance interoperability by reducing reliance of high maintenance local code sets, most existing software packages were developed prior to the existence of such vocabularies. For this reason, the recommendations and requirement to utilize such standard vocabularies should be phased in over time as significant changes to existing databases and applications may be required to utilize these vocabularies to their full potential.</p>
Section V: Questions Regarding the Interoperability Standards Advisory	5-3. [General] For sections I through IV, what “purposes” are missing? Please identify the standards or implementations specifications you believe should be identified as the best available for each additional purpose(s) suggested and why.	AIRA would like to see Immunization Registry Reporting be broken up into two sections: 1) Vaccination Administration Reporting, and 2) Patient Vaccination History/Forecast Query. These use cases both use the same implementation specification, but the purposes are distinct and can be implemented independent of one another. For example, Vaccination Administration Reporting has been part of MU phases 1 and 2, but Patient Vaccination History/Forecast Query has not been.
Section V: Questions Regarding the Interoperability Standards Advisory	<b>5-13 [Section I]</b> If a preferred or specific value set exists for a specific purpose and the standard adopted for that purpose, should it be listed in the “implementation specification” column or	AIRA would expect specific value sets to be defined by the implementation specification and likely don’t need to be called out in these tables. At best, they would contain the same data in multiple locations. At worst, they would conflict.



	should a new column be added for value sets?	
Section V: Questions Regarding the Interoperability Standards Advisory	<b>5.18 [Section IV]</b> Should specific HL7 message types be listed? Or would they be applicable to other purposes as well? If so, which ones and why?	AIRA believes that specific message types required to fulfill a purpose should be defined in the implementation specifications themselves rather than called out in this document.