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May 18, 2015

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

RE: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) definition, and ONC Health IT Certification Program Modifications.

Dear Dr. DeSalvo,

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on ONC's **2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) definition, and ONC Health IT Certification Program Modifications**. As a member organization with more than 250 members from 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.

AIRA members strongly support the inclusion of immunization query functionality in the 2015 CEHRT proposed rule. Currently, 28 IIS (approximately 52% of reporting systems) report to CDC that they have query capabilities in production today using HL7 2.5.1. We anticipate that this proportion will grow close to 100%, if not reach 100% of all IIS by 2018. AIRA also welcomes a longer conversation about expanding the use of NDC codes as a more detailed code set for immunizations, although we suggest requiring both NDC and CVX/MVX in the current proposed rule. We provide detailed suggestions and recommendations on the following pages, organized by page number and section within the CEHRT proposed rule. Please contact Rebecca Coyle, AIRA's Executive Director, with any questions: coyle@immregistries.org.

AIRA greatly appreciates the efforts of ONC to encourage thorough alignment with standards through this certification process, and we look forward to continuing to partner to improve interoperability broadly.

Sincerely,

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

Comments on the ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria

By: AIRA

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Base EHR, Page 16811	<p>TABLE 2—2015 EDITION PROPOSED CERTIFICATION CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3—Continued</p> <p>§ 170.315(f)(1) Transmission to Immunization Registries. Not included Objective 8</p> <p>Footnote 9 below states:</p> <p>For the public health certification criteria in § 170.315(f), technology would only need to be certified to those criteria that are required to meet the options the provider intends to report in order to meet the proposed Objective 8: Public Health and Clinical Data Registry Reporting.</p>	<p>AIRA is concerned that implementers may be confused by the table on page 16810-16811. It appears to be contradictory that Transmission to Immunization Registries in the table above says "Not Included", but the footnote 9 below states:</p> <p>For the public health certification criteria in § 170.315(f), technology would only need to be certified to those criteria that are required to meet the options the provider intends to report in order to meet the proposed Objective 8: Public Health and Clinical Data Registry Reporting.</p> <p>The footnote suggests that if providers chose immunization registry reporting as a measure, it would be included in the base EHR. AIRA requests that the final rule clarify the inclusion and timing of these measures.</p>
<p>Means of Transmission, Page 16850</p> <p>SOAP Standard, Page 16863</p>	<p>2015 Edition Health IT Certification Criterion § 170.315(f)(1) (Transmission to immunization registries)</p> <p>SOAP Transport and Security Specification and XDR/XDM for Direct Messaging 2015 Edition Health IT Certification Criterion § 170.315(h)(3) (SOAP Transport and Security Specification and XDR/XDM for Direct Messaging) We propose to adopt a 2015 Edition certification criterion for electronic transmission that would</p>	<p>AIRA would like to acknowledge that the selected transport standard in the IIS community is SOAP/Web Services (http://www.cdc.gov/vaccines/programs/iis/technical-guidance/SOAP/services.html), leveraging a common WSDL (http://www.cdc.gov/vaccines/programs/iis/technical-guidance/SOAP/wSDL.html) to support the standard interface. Although the majority of IIS have embraced this transport mechanism, and we believe more will continue to do so, AIRA would like to confirm that transport will continue to be allowed to be specified at the state or</p>

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	include the capability to send and receive according to the Transport and Security Specification (also referred to as the SOAP-Based Secure Transport RTM adopted at § 170.202(c)) and its companion specification XDR and XDM for Direct Messaging Specification adopted at § 170.202(b) We previously adopted this capability for the 2014 Edition at § 170.314(b)(1), (b)(2) and (h)(3).	jurisdictional level in accordance with local law and policy.
“Minimum Standards” Code Sets, Page 16850	We propose to adopt a 2015 Edition “transmission to immunization registries” certification criterion that is revised in comparison to the 2014 Edition “transmission to immunization registries” criterion (§ 170.314(f)(2)). We propose to adopt an updated IG, require National Drug Codes (NDC) for recording administered vaccines, require CVX codes for historical vaccines...	<p>AIRA supports the adoption of the updated IG, specifically the HL7 2.5.1 release 1.5 guide.</p> <p>We also support 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>As such, consider adding MVX to the list of “Minimum Standards” Code Sets.</p> <p>Regarding administered vaccines, AIRA advocates for requiring the preferred code sets of CVX and MVX, as well as supporting NDC for administered dose reporting.</p>
NDC Codes, Page 16851	NDC codes for vaccines include a portion that identifies the product, and thus cannot be used to code historical vaccinations of unknown formulation. Historical vaccinations are self-reported vaccinations given prior to the office visit. Patients can report historical vaccinations to providers without supporting documentation, such as a written or electronic vaccination history,	<p>As stated above, we agree with option 1, to use CVX to submit historical doses.</p> <p>However, AIRA believes it is important to define the concepts of “administered” and “historical”. Per AIRA’s Modeling of Immunization Registry Operations Workgroup (MIROW) Manual, Chapter 7 on Data Quality, administered and historical are differentiated as follows:</p>

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	<p>and therefore the provider does not know the manufacturer and/or formulation of the product. In terms of options for recording historical vaccinations of unspecified/unknown formulation, we solicited comments on two options in the Voluntary Edition proposed rule: • Option 1: Continue to use CVX codes for historical vaccinations only; • Option 2: Use the NDC syntax and create a new value set for the product portion of the code for vaccines of unspecified formula (e.g., influenza vaccine of unspecified formula) for historical vaccinations (resulting in an “NDC-like” code).</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"> • In this case, expanded set of data items for a Vaccination Event Submission would be expected (this is the Best Practice -- see BRI05R1, chapter 5). • 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 BRI05R2, chapter. <ul style="list-style-type: none"> ○ 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. ○ Limited EHR capacity. In some cases, EHR that IIS-AO uses does not 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. <ul style="list-style-type: none"> ▪ This situation would be for a limited time period, as established by the IIS. ○ Birth Doses. HepB and other hospital birth doses may not

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		<p>have all required data elements available.</p> <ul style="list-style-type: none"> ○ Notes: <ul style="list-style-type: none"> ▪ 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. ▪ 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. <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"). In this case, a reduced set of data items for a Vaccination Event Submission would be expected.</p>
NDC Codes, Page 16851	We believe NDC codes for vaccines may be best suited to support immunization inventory management, as well as for providing the benefits stated above for 2D barcoding and	Although NDC codes are used increasingly throughout IIS for vaccine inventory, ordering, and shipping, they require significant maintenance and may impose an unnecessary burden on EHRs and IIS alike.

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	<p>patient safety. Both the HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 and the C-CDA Release 2.0 IG support coding of immunizations using both CVX and NDC codes. CDC also provides a publicly available mapping of NDC codes for vaccines to CVX codes.</p>	<p>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 many IIS, and would also necessitate additional maintenance to the IIS as the codes are added and updated. There are also continued challenges with dual NDC codes on external packaging and on unit of use, so additional mapping functionality would be essential.</p> <p>It is also unclear whether NDC codes would be appropriate for use with bidirectional (patient history/forecast query) message exchanges. The CEHRT rule 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 code sets for administered immunizations, while also encouraging and supporting the use of NDC codes for administered immunizations, as NDC continues to be used in 2D barcoding and some inventory decrementing. AIRA does not support the introduction of “NDC-like” codes.</p> <p>AIRA would also like to collaborate in evaluating the benefits and costs of transitioning to NDC as a potential replacement code set for administered immunizations in the future.</p>
Bidirectional Exchange, Page 16852	We believe that bidirectional exchange between health IT and immunization registries is	AIRA strongly supports the inclusion of bidirectional exchange with immunization registries in the CEHRT rule. As mentioned

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	<p>important for patient safety and improved care. Immunization registries can provide information on a patient's immunization history to complement the data in the EHR. Immunization registries also provide immunization forecasting recommendations according to the ACIP's recommendations. This information allows for the provider to access the most complete and up-to-date information on a patient's immunization history to inform discussions about what vaccines a patient may need based on nationally recommended immunization recommendations. Provided the discussion above, we propose that, for certification to this criterion, a Health IT Module would need to enable a user to request, access, and display a patient's immunization history and forecast from an immunization registry in accordance with the HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5. We welcome comment on this proposal.</p>	<p>in our introductory letter, over half of IIS report to CDC that they currently have HL7 2.5.1 query functionality live in production, and this number is increasing rapidly as IIS fully adopt HL7 2.5.1 release 1.5.</p>
<p>Immunization History Reconciliation, Page 16852</p>	<p>We also welcome comments on whether we should include an immunization history information reconciliation capability in this criterion and the factors we should consider regarding the reconciliation of immunization history information.</p>	<p>AIRA believes that the inclusion of immunization history information reconciliation capability would add significant value to the EHR product while lowering the burden on the end user, who otherwise would need to rekey the queried data into their EHR manually. Inclusion of this capability would improve patient safety and up to date status through ensuring an accurate clinical record in the EHR.</p> <p>AIRA's MIROW Guide on vaccine level deduplication can be used as a guide and best</p>

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		practice resource for immunization history information reconciliation: (http://www.immregistries.org/resources/AIR_A-BP_guide_Vaccine_DeDup_120706.pdf).
HL7 Version 2.5.1, Page 16852	We understand that the HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 we are proposing to adopt for this criterion provides improvements that support bidirectional exchange between health IT and immunization registries, including segments for querying a registry, receiving information, and sending a response to the registry.	AIRA would like to request a greater specificity regarding standardized messaging in the rule. Version 1.5 of the CDC implementation guide contains multiple different profiles. While the ONC rule calls out functionality required (vaccination administration event submission and the ability to query/receive/display a patient history and forecast), it doesn't call out the specific profiles that Health IT modules must support. To support vaccination administration event submission, a compliant EHR system should use the Z22 profile to submit the event and the IIS should response using the Z23 profile. To support the exchange of a patient history and forecast, a compliant EHR system should use the Z44 profile to submit the query request and the IIS should respond with one of the Z23, Z42 or Z33 profiles as per Table 11-2 of the guide.
Race and Ethnicity, Page 16871	We note that for race and ethnicity a Health IT Module must be able to express both detailed races and ethnicities according to the "Race & Ethnicity—CDC" code system and the aggregate OMB code for each race and ethnicity identified by the patient.	The section on patient demographics states "The "Race & Ethnicity—CDC" code system in PHIN VADS (at a minimum, Release 3.3.9) permits a much more granular structured recording of a patient's race and ethnicity with its inclusion of over 900 concepts for race and ethnicity. The recording and exchange of patient race and ethnicity at such a granular level can facilitate the accurate identification and analysis of health disparities based on race and ethnicity." It is not clear if the word "exchange" means that HL7 mediated integrations using the CDC version 1.5 implementation guide must have the capability to exchange all 900+ codes or if it is sufficient to use the aggregated OMB standard values for exchange. AIRA believes that the maintenance of 900+ codes by both IIS and EHR would create unnecessary burden with limited return on investment, so

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		we would support the use of the aggregated OMB codes.
NDC to CVX Mapping, Page 16872	We believe that it would not be a heavy burden to map from an NDC code to a CVX code because a mapping from NDC codes to CVX codes is publicly available.	AIRA believes mapping NDC to CVX may, in fact, be a more challenging effort in a dynamic environment. Given that new NDCs can be created at the discretion of vaccine manufacturers, it may be more challenging to be <i>timely</i> in maintaining a complex mapping table that can then be leveraged by all EHRs (and their providers) as well as IIS. New NDCs (and their associated mapping) would need to be recognized and added to all systems prior to a vaccine becoming available and needing to be messaged to ensure uninterrupted data exchange. Similarly, maintenance would also be required to retire frequently changing NDC codes as well.
Common Clinical Data Set, Page 16872	We propose to include immunizations in the “Common Clinical Data Set” for 2015 Edition certification. As described in more detail in the preamble for the “transmission to immunization registries” certification criterion in section III.A.3, the C-CDA Release 2.0 can support NDC codes as a translational data element, but the CVX code is required to accompany it.	AIRA notes that the first half of the sentence about IIS transmission doesn’t seem to align with the second half referring to C-CDA R2 since IIS transmission is based on HL7 V2 and not C-CDA R2.
Future certification criteria, Page 16873	We believe this proposal best addresses the full range of health IT that has and might be certified to adopted certification criteria now and in the future	While the Meaningful Use incentive program will conclude with Stage 3 (per the CMS rule), it’s not entirely clear if the standards named in certification rule will be updated in future versions. Please clarify if the EHR certification program will continue to evolve in the future.
MVX Codes, Page 16893	The MVX table includes both active and inactive vaccines available in the U.S.	AIRA wishes to clarify that the MVX code set isn’t a table of vaccines, but rather vaccine manufacturers.