AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

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April 28, 2014

Steven Posnack, Director
Federal Policy Division, Office of Policy and Planning
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: 2015 Edition EHR Certification Criteria Proposed Rule, RIN 0991-AB92
Submitted electronically at http://www.regulations.gov/#!submitComment;D=HHS-OS-2014-0002-0001

Dear Mr. Posnack:

The American Immunization Registry Association (AIRA) is a membership organization that promotes the development and implementation of immunization information systems (IIS) as an important tool in preventing and controlling vaccine preventable diseases. The organization provides a forum through which IIS programs, and interested organizations, individuals and communities combine efforts, share knowledge, and promote activities to advance IIS and immunization programs. There is a long history of success among AIRA members in exchanging data with Electronic Health Record (EHR) systems, schools, health plans, and other public health organizations. Accordingly, AIRA members are keenly interested in helping the Meaningful Use (MU) efforts succeed in furthering the goal of exchanging data between EHRs and IIS.

AIRA has used the public comment template to comment below on proposed certification criterion or criteria, as well as to respond to specific requests for comments. AIRA also has some general comments for consideration by the Office of the National Coordinator for Health Information Technology (ONC):

- AIRA asks for clarification on the purpose of voluntary certification for providers. If certification of EHR products is voluntary, how will eligible providers (EPs) know if a product can be used to meet MU 3 requirements as it seems as though some of the voluntary certification requirements may exceed MU 3 requirements.
- AIRA would like to offer subject matter expertise in areas such as clinical information reconciliation and incorporation, clinical quality measures for immunization, Blue Button + development, disaster recovery, and any other areas in which our expertise is relevant and helpful. AIRA commends the ONC on its commitment to serving public health outcomes through the use of health information technologies and would like to continue and increase our collaborative efforts moving forward.

We sincerely appreciate the opportunity to provide comments on the Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements, and hope that our comments are helpful. If you have any questions regarding our comments or need additional information, please contact Rebecca Coyle at coyler@immregistries.org.

Sincerely,

Frank Caniglia, President
AIRA

Rebecca Coyle, Executive Director
AIRA

AIRA COMMENTS ON THE VOLUNTARY 2015 EDITION ELECTRONIC HEALTH RECORD (EHR) CERTIFICATION CRITERIA; INTEROPERABILITY UPDATES AND REGULATORY IMPROVEMENTS

§ 170.315(a)(10) (Clinical decision support)
MU Objective Use clinical decision support to improve performance on high-priority health conditions.
2015 Edition EHR Certification Criteria (10)Clinical decision support.(i)Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) At least one demographic specified in paragraph (a)(5)(i) of this section; (E) Laboratory tests; and (F) Vital signs. (ii)Linked referential clinical decision support. (A) EHR technology must be able to: (1) Electronically identify for a user diagnostic and therapeutic reference information; or (2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (3). (B) For paragraph (a)(10)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section. (iii) Clinical decision support configuration. (A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role. (B) EHR technology must enable interventions to be electronically triggered: (1) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section. (2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(i)(B) of this section. (3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4)(i)(A)(1) of this section. (iv)Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(10)(i) through (iii)of this section must automatically and electronically occur when a user is interacting with EHR technology. (v)Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources: (A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section: (1) Bibliographic citation of the intervention (clinical research/guideline); (2) Developer of the intervention (translation from clinical research/guideline); (3) Funding source of the intervention development technical implementation; and (4) Release and, if applicable, revision date(s) of the intervention or reference source.

§ 170.315(a)(10) (Clinical decision support)

(B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(vi) Decision support – knowledge artifact. Electronically process clinical decision support knowledge artifacts in accordance with the standard specified at § 170.204(d).

(vii) Decision support – service. Enable a user to electronically make an information request with patient data and receive in return electronic clinical guidance in accordance with the standard specified at § 170.204(e).

Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *Yes*

Public Comment Field:

- *At least one major ambulatory EHR vendor is accessing a clinical decision support (CDS) service for immunization in their latest production version which uses HeD standards (the ICE Open Source product used by eClinicalWorks). The service they are using was developed cooperatively by a public-private partnership which included two public health agencies. HeD standards provide a more specialized way to enable this functionality, and likely IIS will move to supplement or replace their CDS capabilities to use these standards. Based on these facts, we suggest that the standards behind the CDS measure for immunization be loosened (but not eliminated) to include either HeD or the receipt of CDS information within an HL7 RSP message.*
- *Rulemaking should be explicit that CDS can be external to the EHR.*
- *Rulemaking should include an explicit requirement that CDS service provide accurate results in accordance with The Advisory Committee on Immunization Practices (ACIP) recommendations.*

§ 170.315(a)(17) (Patient-specific education resources)

MU Objective

Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

2015 Edition EHR Certification Criterion

(17) Patient-specific education resources**.** EHR technology must be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests:

(i) In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (3); and

(ii) By any means other than using the standard specified in § 170.204(b).

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *Yes*

Public Comment Field:

The NPRM seeks comment on whether the EHR certification criteria should maintain a requirement for EHR technology to demonstrate the capability to electronically identify for a user patient-specific education resources using Infobutton.

- *AIRA supports the use of InfoButton to retrieve vaccine information statements (VIS) from repositories in a standards-based way.*

§ 170.315(b)(1) (Transitions of care)

§ 170.315(b)(1) (Transitions of care)

MU Objective

The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

2015 Edition EHR Certification Criteria

(1) Transitions of care. (i) Send and receive via edge protocol. EHR technology must be able to electronically:

(A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) and that leads to such summaries being processed by a service that has implemented the standard specified in §170.202(a); and

(B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) from a service that has implemented the standard specified in §170.202(a).

(ii) Receiving accuracy. EHR technology must meet or exceed the standard specified at §170.212(a)

(iii) Display.

(A) EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: §170.205(a)(1) through (4).

(B) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at §170.205(a)(3).

(iv) Create. (A) Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at §170.205(a)(4) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(1) Encounter diagnoses. The standard specified in §170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(3);

(2) Immunizations. The standard specified in §170.207(e)(2);

(3) Cognitive status;

(4) Functional status;

(5) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information;

(6) Inpatient setting only. Discharge instructions; and

(7) Unique Device Identifier(s) for a patient's implantable device(s).

(B) Patient matching data quality. EHR technology must be capable of creating a transition of care/referral summary that includes the following data and, where applicable, represent such data according to the additional constraints specified below:

(1)Data. first name, last name, middle name (or middle initial in cases where only it exists/is used), suffix, date of birth, place of birth, maiden name, current address, historical address, phone number, and sex.

(2) Constraint. Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule v. 2.1.0.

(3) Constraint. Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, PHD, ESQ). If no suffix exists, the field should be entered as null.

(4) Constraint. Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.

(5) Constraint. Represent current and historical address information, including the street address, city, state, zip code, according to the U.S. Postal Service format;

(6) Constraint. Represent phone number (home, business, cell) in the ITU format specified in ITU-T E.123 and ITU-T E.164. If multiple phone numbers are present, all should be included.

(7)Constraint. Represent sex according to the HL7 Version 3 ValueSet for Administrative Gender.

Preamble FR Citation: 79 FR 10896	**Specific questions in preamble?** *Yes*

Public Comment Field:

The NPRM seeks comment on the proposed standardized data to improve patient matching, including whether other data or constraints on proposed data should be modified to better support patient matching practices and work flow.

§ 170.315(b)(1) (Transitions of care)

- *AIRA supports the data elements and constraints suggested by ONC for patient matching.*

The NPRM also asks for comments on the Patient Identification and Matching Initial Findings (Dec 2013).

- *While this report was useful, it was EHR-centric and did not really address HIE-related issues of patient matching which are important and can directly or indirectly affect IIS. The table below lays out some issues with respect to HIO and patient identity integrity, and some comments and suggestions related to resolving the issues:*

Issue	Comments
Record ownership is distributed: Though it is a matter of policy which can vary, usually records are owned by the organizations that contribute the data (or sometimes the patients themselves, who in fact own the underlying data) rather than the HIO which has stewardship over data it receives. HIOs usually place high priority on maintaining the integrity of the source data in its original form, though some HIOs consolidate data together for presentation or transport. HIOs rarely have access to the patient or even the source systems.	For purposes of demographic matching the HIO can only work with the data that are provided unless there is provision for follow-up with the organization that submitted the data. Explicit HIO policy incorporated (even if only by reference) into the data sharing agreement must identify the responsibilities and limitations of the HIO and downstream recipients of data.
Source data are inconsistent and often conflicting: Data come from multiple, simultaneous sources. It is not possible to discern which data are "correct" - even data that appear to be more recent may not be more current.	HIOs need to keep in mind that the purpose of the EMPI is to enable accurate matching of patients, not to necessarily to be the authoritative source of demographic (or other) information. Multiple sets of demographic data correctly associated with the same patient help build a more functional record. HIOs should allow for all demographic data for a patient, whether historical or current, to be correctly associated with the same patient and to be available and used for matching purposes. HIOs should work to ensure that any known errors are corrected at the source to enable optimal performance of EMPI demographic matching algorithms. That being said, HIOs can develop and institute shared, distributed responsibility for resolving ambiguous patient matches with policies and tools that allow HIO participants to review ambiguous matches based on data *they* submitted. But caution is advised: an HIO needs to determine carefully how much HIO data (ostensibly from other organizations) from *possible* patient matches can be shown *to an organization* for the purpose of trying to establish a good match to new or existing data. Whenever possible, "overlaps" (also known as "linkages" or

§ 170.315(b)(1) (Transitions of care)	
	"crossovers") should be worked on by HIO staff.
HIO operations may cross state lines: State law or regulations may place additional restrictions on how patient data is treated above HIPAA, the HITECH Act, and other applicable Federal laws and regulations, such as in regard to sensitive health information (e.g., drug and alcohol abuse, mental health, and HIV and AIDS).	EMPI demographic matching activities in and of themselves should not provide any additional constraints. Several ONC activities have studied issues related to interstate health information exchange including consent and privacy issues and patient matching, but they have not focused on patient matching in an HIE environment.
Inconsistencies across HIO participants: The tools, business rules, policies, and training regimens used to collect and transmit the data are usually unknown to the HIO and are generally inconsistent across the HIO participants.	As more participants join HIOs, these issues will only increase. An HIO should develop explicit documentation related to its expectations of its participant organizations, their business processes, and data. A common participation agreement for the HIO should include policies related to appropriate use, security, quantity, quality and treatment of data to be used for demographic matching purposes.
Breach notification may become much more complex: As data leaves an organization and goes through the HIO to other organizations, breaches that occur within organizations that ultimately consume data from the HIO. The breach notifications might need to be made by multiple parties, including the source of the information, the HIO, and the HIO participant where the breach actually occurred.	HIOs should establish incident handling, and response (including breach notification) processes for data that are inappropriately released both by the HIO and an HIO participant (after consultation with relevant Federal, State and local laws and regulations), as well as post-incident recovery processes.
"False positives" may have much deeper ramifications: Any false positive (*i.e.,* information for two *different* people which appears to be a demographic match representing the same individual) results in an overlaid record and creates the potential for serious patient harm. When the match occurs some distance from the patient and the source(s) where the data originated, there is often little opportunity to notice, let alone correct the error. This is especially true when the recipient of the information has no prior relationship with the patient for whom data (as a result of the demographic match) is now being presented.	HIOs need to be very careful when matching and associating and linking records together for a demographic match and need to err on the side of caution. HIOs should adopt strict demographic record matching policies. HIOs need to establish governance and stewardship policies and procedures that address what happens if a false positive linkage or association is created.

§ 170.315(b)(2) (Clinical information reconciliation and incorporation)
MU Objective
The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

§ 170.315(b)(2) (Clinical information reconciliation and incorporation)

2015 Edition EHR Certification Criteria

(2) Clinical information reconciliation and incorporation**.** (i) Correct patient**.** Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(4), EHR technology must be able to demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

(ii) Reconciliation**.** Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:

(A) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date;

(B) Enable a user to create a single reconciled list of medications, medication allergies, or problems;

(C) Enable a user to review and validate the accuracy of a final set of data; and

(D) Upon a user's confirmation, automatically update the list, and electronically incorporate the following data expressed according to the specified standard(s):

(1) Medications. At a minimum, the version of the standard specified in § 170.207(d)(2);

(2) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);

(3) Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(2).

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *Yes*

Public Comment Field:

- *When EHRs consume query response, they should be mindful to maintain provenance. AIRA offers our expertise and assistance for this area for 2017 Edition rulemaking.*

§ 170.315(b)(6) (Data portability)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(6) Data portability**.** Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(4) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(i) Encounter diagnoses**.** The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);

(ii) Immunizations**.** The standard specified in § 170.207(e)(2);

(iii) Cognitive status;

(iv) Functional status;

(v) Ambulatory setting only**.** The reason for referral; and referring or transitioning provider's name and office contact information;

(vi) Inpatient setting only**.** Discharge instructions; and

(vii) Unique Device Identifier(s) for a patient's Implantable Device(s).

Preamble FR Citation: 79 FR 10902	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.315(b)(6) (Data portability)

- *AIRA supports the concept that data should be able to move from one EHR to another, and to and from IIS.*
- *The NPRM solicited comment on whether this certification criterion should be renamed "data migration." Data Migration has specific meaning and this term change could cause confusion, therefore AIRA recommends against changing the name of this certification criterion from "Data Portability" to "Data Migration."*

§ 170.315(c)(1) (Clinical quality measures – capture and export)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(1) Clinical quality measures—capture and export**.** (i) Capture**.** For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."

(ii) Export**.** EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.

Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *Yes*

Public Comment Field:

- *Immunization-related CQM do not currently match well with ACIP recommendations. AIRA offers its subject matter expertise to review and advise on changes to the immunization-related CQM to bring them into alignment with ACIP recommendations.*

§ 170.315(e)(1) (View, download, and transmit to third party)

MU Objective

EPs

Provide patients, and their authorized representatives, the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

EHs and CAHs

Provide patients, and their authorized representative, the ability to view online, download, and transmit information about a hospital admission.

2015 Edition EHR Certification Criterion

(1) View, download, and transmit to 3rd party. (i) Patients (and their authorized representatives) must be able to use EHR technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Access to these capabilities must be online and through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(A) View. Patients (and their authorized representatives) must be able to use EHR technology to electronically view in accordance with the standard adopted at § 170.204(a)(2), at a minimum, the following data:

(1) The Common MU Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).

(2) Ambulatory setting only. Provider's name and office contact information.

§ 170.315(e)(1) (View, download, and transmit to third party)

(3) Inpatient setting only. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(B) Download.

(1) Patients (and their authorized representatives) must be able to use EHR technology to electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) in only human readable format, in only the format specified in accordance to the standard adopted at § 170.205(a)(4), or in both formats.

(2) When downloaded according to the standard adopted at § 170.205(a)(4), the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(i) Ambulatory setting only. All of the data specified in paragraph (e)(1)(i)(A)(1) and (2) of this section and Unique Device Identifier(s) for a patient's implantable device(s).

(ii) Inpatient setting only. All of the data specified in paragraphs (e)(1)(i)(A)(1) and (3) of this section and Unique Device Identifier(s) for a patient's implantable device(s).

(3) Inpatient setting only. Patients (and their authorized representatives) must be able to electronically download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(1) of this section).

(C) Transmit to third party. Patients (and their authorized representatives) must be able to:

(1) Enter a 3rd party destination of their choice to electronically transmit:

(i) The ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) created in paragraph (e)(1)(i)(B)(1) of this section in accordance with the standard specified in § 170.202(a).

(ii) Inpatient setting only.Electronically transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with the standard specified in § 170.202(a).

(2) Accomplish a transmission of their ambulatory summary or inpatient summary through a method that conforms to the standard specified at §170.202(e) and that leads to such summary being processed by a service that has implemented the standard specified in §170.202(a).

(ii) Activity history log. (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:

(1) The action(s) (i.e., view, download, transmission) that occurred;

(2) The date and time each action occurred in accordance with the standard specified at § 170.210(g);

(3) The user who took the action; and

(4) The addressee to whom an ambulatory summary or inpatient summary was transmitted and whether that transmission was successful (or failed).

(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at §170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

Preamble FR Citation: 79 FR10906	**Specific questions in preamble?** *Yes*

Public Comment Field:

- *In the C-CDA there may be more information than is necessary for the IIS use case, and in fact extraneous data included in a C-CDA is detrimental to the use case which wants to prevent unnecessary data from being provided along with the immunizations. AIRA is open to and interested in working with C-CDA developers to refine the information produced for our use case.*

§ 170.315(e)(2) (Ambulatory setting only – clinical summary)

MU Objective

Provide clinical summaries for patients for each office visit.

2015 Edition EHR Certification Criterion

(2) Ambulatory setting only—clinical summary. (i) Create. Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at § 170.205(a)(4).

(ii) Customization. Enable a user to customize the data included in the clinical summary.

(iii) Minimum data from which to select. EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary:

(A) Common MU Data Set (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set);

(B) Medications administered during the visit. At a minimum, the version of the standard specified in § 170.207(d)(2);

(C) Immunizations administered during the visit. At a minimum, the version of the standard specified in § 170.207(e)(2);

(D) Diagnostic tests pending and future scheduled tests. At a minimum, the version of the standard specified in § 170.207(c)(2);

(E) The provider's name and office contact information; date and location of visit; reason for visit; clinical instructions; future appointments; referrals to other providers; and recommended patient decision aids; and

(F) Unique Device Identifier(s) for a patient's Implantable Device(s).

Preamble FR Citation: 79 FR10907	**Specific questions in preamble?***Yes*

Public Comment Field:

The NPRM states: "We propose to adopt a 2015 Edition ''clinical summary'' certification criterion that revises the 2014 Edition version. Specifically, we propose to reflect the clarifications we provided in FAQ 33,84 require the use of CVX codes for immunizations, and reference the updated Consolidated CDA version (Draft Standard for Trial Use, Release2.0) in this criterion for consistency across our 2015 Edition and for the other reasons stated already in the proposed 2015 Edition ToC certification criterion.

- *AIRA supports the clarification that the updated Consolidated CDA version (Draft Standard for Trial Use, Release 2.0) should specify and require the use of CVX codes as well as MVX codes (not expected for historical doses).*

§ 170.315(f)(1) (Immunization information)

MU Objective

Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

2015 Edition EHR Certification Criterion

(1) Immunization information. Enable a user to electronically record, change, and access immunization information.

Preamble FR Citation: 79 FR10908	**Specific questions in preamble?***No*

Public Comment Field:

The NPRM proposes to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version. AIRA supports this proposal as IIS continue to progress beyond current criterion in anticipation of Stage 3. Initial data from the Quarterly IIS Meaningful Use survey administered by the CDC show that twenty-two (22) IIS are engaged in some level of Query/Response (QBP/RSP) efforts as of December 2013. Of the twenty-two (22), fourteen (14) are in production. Additionally, the CDC WSDL being implemented in IIS supports both VXU submission and Query/Response. We also know that 100% of IIS can produce clinical decision support via their IIS User Interface, so the functionality to produce decision support already exists. The functionality to interoperate may need to be built, but in the case of immunization-based CDS, the logic is more complicated than the population of the message, so the primary hurdle for implementation has already been overcome. As Stage 3 is several years in the future, AIRA strongly believes that the vast majority of IIS will be prepared to support Query/Response and CDS in a standard way.

§ 170.315(f)(2) (Transmission to immunization registries)	
MU Objective Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.	
2015 Edition EHR Certification Criterion (2) Transmission to immunization registries EHR technology must be able to electronically create immunization information for electronic transmission in accordance with: (i) The standard and applicable implementation specifications specified in § 170.205(e)(4); and (ii) At a minimum, the version of the standard specified in § 170.207(e)(2).	
Preamble FR Citation: 79 FR10908	**Specific questions in preamble?** *Yes*

Public Comment Field:

- *AIRA supports the adoption of HL7 Version 2.5.1 Implementation Guide for Immunization Messages, Release 1.5, and agrees that this update promotes greater interoperability between immunization information systems and EHR technologies.*
- *The NPRM seeks comments on the maturity of bidirectional immunization data exchange activities and whether ONC should propose to include bidirectional immunization data exchange as part of the 2015 Edition and/or 2017 Edition. As stated in comments on § 170.315(f)(1), initial data from the Quarterly IIS Meaningful Use survey administered by the CDC show that twenty-two (22) IIS are engaged in some level of Query/Response (QBP/RSP) efforts as of December 2013. Of the twenty-two (22), fourteen (14) are in production. Additionally, the CDC WSDL being implemented in IIS supports both VXU submission and Query/Response. We also know that 100% of IIS can produce clinical decision support via their IIS User Interface, so the functionality to produce decision support already exists. The functionality to interoperate may need to be built, but in the case of immunization-based CDS, the logic is more complicated than the population of the message, so the primary hurdle for implementation has already been overcome. As Stage 3 is several years in the future, AIRA strongly believes that the vast majority of IIS will be prepared to support bidirectional Query/Response and CDS in a standard way.*
- *AIRA strongly supports ongoing use of CVX codes for vaccine identification, especially when the specific product is not known. It also strongly supports use of NDC codes for reporting administered doses of vaccine (as opposed to historic dose records).*
  There are a number of key requirements that must be supported by HL7 messaging of immunizations. These include:
  - *Accurate identification of vaccine administered*
  - *Support for clinical decision support for validation of administered vaccines and forecasting of next doses due*
  - *Tracking of federally funded vaccine usage for accountability*
  - *Supporting inventory management of vaccines (ordering and usage) including integration of 2-D barcoding*
  - *Support for recall of recipients of specific vaccine lots*

  The Case for CVX/MVX

  The coding system must support the ability to report historic records of immunization where the generic type of vaccine administered is known, but the specific product is not. For instance an immunization card may indicate that a child received a HIB vaccine. At the same time, the coding system must support the ability to report a specific product, when known. For example, a clinician administered a HIB vaccine, HIB PRP-T. Finally, it is important to be able to identify the trade name of the vaccine, when known. CVX (CDC vaccine codes) and MVX (manufacturer codes) were developed to support this range of granularity. CVX has codes for vaccines of unspecified formulation (Hep B, unspecified formulation) and for specific products (Hep B, adult formulation). When combined with an MVX, one can identify Recombivax, adult formulation. No other coding system currently supports this ability to cover historic doses and administered doses.

  CVX/MVX support the first 2 bullet points above, but are less facile supporting the latter 3.

The Case for NDC

NDC codes are composed of 3 components:

- *Labeller – the entity packaging the product*
- *Product – the actual vaccine*
- *Package – the presentation of the product (ie syringe vs vial)*

There are NDC for the unit of use (syringe) and unit of sale (carton of syringes).

NDC codes are used for ordering vaccines, an important function supported by many Immunization Information Systems (IIS). In addition, NDC codes are a component of the 2-D barcoding now being added to vaccines. This will allow clinicians to scan the vaccine being administered. This is being piloted in a number of IIS. CDC is working with FDA to maintain a set of tables that allow mapping between unit of use and unit of sale NDC and CVX/MVX codes. This will facilitate IIS ordering of vaccines through the VTrckS program, linking that vaccine into inventory, and linking the vaccine administered to that inventory.

NDC codes are published by the FDA and provide granular information about the vaccine, indicating such information as components, strengths and amounts. For instance, Prevnar 7 has the following attributes:

Use Unit Labeler	Use Unit Product	Use Unit Package	Use Unit Prop Name	Use Unit Generic Name	Use Unit Labeler Name	Use Unit Start Date	Use Unit End Date	Use Unit Prod Form	Use Unit Pack Form	Use Unit Ingredient Names	Use Unit Strengths	Use Unit Strength Units	UseUnitStrengthDenominatorUnit
0005	1970	49	Prevnar	PNEUMOCOCCAL 7-VALENT	Wyeth Pharmaceutical Division of Wyeth Holdings Corporation, a subsidiary of Pfizer Inc.	20000301		INJECTION, SUSPENSION	SYRINGE	See Ingredient Names Below[1]	4; 4; 8; 4; 4; 4; 4	ug; ug; ug; ug; ug; ug; ug	mL

[1]STREPTOCOCCUS PNEUMONIAE TYPE 14 CAPSULAR POLYSACCHARIDE DIPHTHERIA CRM197 PROTEIN CONJUGATE ANTIGEN; STREPTOCOCCUS PNEUMONIAE TYPE 9V CAPSULAR POLYSACCHARIDE DIPHTHERIA CRM197 PROTEIN CONJUGATE ANTIGEN; STREPTOCOCCUS PNEUMONIAE TYPE 6B CAPSULAR POLYSACCHARIDE DIPHTHERIA CRM197 PROTEIN CONJUGATE ANTIGEN; STREPTOCOCCUS PNEUMONIAE TYPE 4 CAPSULAR POLYSACCHARIDE DIPHTHERIA CRM197 PROTEIN CONJUGATE ANTIGEN; STREPTOCOCCUS PNEUMONIAE TYPE 23F CAPSULAR POLYSACCHARIDE DIPHTHERIA CRM197 PROTEIN CONJUGATE ANTIGEN; STREPTOCOCCUS PNEUMONIAE TYPE 19F CAPSULAR POLYSACCHARIDE DIPHTHERIA CRM197 PROTEIN CONJUGATE ANTIGEN; STREPTOCOCCUS PNEUMONIAE TYPE 18C CAPSULAR POLYSACCHARIDE DIPHTHERIA CRM197 PROTEIN CONJUGATE ANTIGEN

The Case Against RxNorm

RxNorm can accurately identify administered vaccines, but does not support the important functionality related to inventory management and integration of 2-D bar coding. Since systems can map from NDC to RxNorm, it is sensible to send the NDC codes in HL7 messages and do the translation on the application side, as needed.

§ 170.315(h)(1) (Transmit – Applicability Statement for Secure Health Transport)	
MU Objective N/A	
2015 Edition EHR Certification Criterion 1) Transmit – Applicability Statement for Secure Health Transport Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(a).	
Preamble FR Citation: 79 FR10914	**Specific questions in preamble?***No*
Public Comment Field: *AIRA's comments for 170.315(h)(1), 170.315(h)(2), 170.315(h)(3) and 170.315(h)(4) are the same. On the matter of transport of immunization data, AIRA reiterates our long standing support for SOAP web services, specifically the CDC Transport Layer Expert Panel (TLEP) WSDL Specifications. While there is a use case for Direct in other medical arenas, there is a strong argument against using Direct in the immunization space, but rather continue to use SOAP web services for immunizations. Direct was considered for an IIS use case by the CDC TLEP, but because Direct does not support synchronous response, which impedes the long term need for Query/Response to support bi-directional communication, SOAP was selected instead of Direct as the recommended transport layer. The December 2013 Quarterly IIS MU Survey referred to above also provides data on transport. Forty-one (41) of fifty-five (55) respondents are engaged in SOAP as their Transport. Of those forty-one, thirty-five (35) are in production, and twenty-three (23) of the forty-one are working directly with the CDC WSDL. By supporting web services as a Stage 3 standard, the Task Force will support better positioning for both IIS and EHRs for Query/Response. We understand that the committee is strongly recommending the use of Direct, but this is only after the committee concluded that Query/Response was not something IIS could support in the time frame necessary for Stage 3. Since we do believe that Query/Response is feasible in this time frame, we maintain (for the reasons stated) that web services continues to be the right strategy and investment for supporting both data submission and query/response between an EHR and an IIS.*	

§ 170.315(h)(2) (Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging)	
MU Objective N/A	
2015 Edition EHR Certification Criterion (2) Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(b).	
Preamble FR Citation: 79 FR10914	**Specific questions in preamble?***No*

Public Comment Field:

AIRA's comments for 170.315(h)(1), 170.315(h)(2), 170.315(h)(3) and 170.315(h)(4) are the same. On the matter of transport of immunization data, AIRA reiterates our long standing support for SOAP web services, specifically the CDC Transport Layer Expert Panel (TLEP) WSDL Specifications. While there is a use case for Direct in other medical arenas, there is a strong argument against using Direct in the immunization space, but rather continue to use SOAP web services for immunizations. Direct was considered for an IIS use case by the CDC TLEP, but because Direct does not support synchronous response, which impedes the long term need for Query/Response to support bi-directional communication, SOAP was selected instead of Direct as the recommended transport layer. The December 2013 Quarterly IIS MU Survey referred to above also provides data on transport. Forty-one (41) of fifty-five (55) respondents are engaged in SOAP as their Transport. Of those forty-one, thirty-five (35) are in production, and twenty-three (23) of the forty-one are working directly with the CDC WSDL. By supporting web services as a Stage 3 standard, the Task Force will support better positioning for both IIS and EHRs for Query/Response. We understand that the committee is strongly recommending the use of Direct, but this is only after the committee concluded that Query/Response was not something IIS could support in the time frame necessary for Stage 3. Since we do believe that Query/Response is feasible in this time frame, we maintain (for the reasons stated) that web services continues to be the right strategy and investment for supporting both data submission and query/response between an EHR and an IIS.

§ 170.315(h)(3) (Transmit – SOAP Transport and Security Specification & XDR/XDM for Direct Messaging)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(3) Transmit – SOAP Transport and Security Specification & XDR/XDM for Direct Messaging Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(c).

Preamble FR Citation:79 FR10914	**Specific questions in preamble?***No*

Public Comment Field:

AIRA's comments for 170.315(h)(1), 170.315(h)(2), 170.315(h)(3) and 170.315(h)(4) are the same. On the matter of transport of immunization data, AIRA reiterates our long standing support for SOAP web services, specifically the CDC Transport Layer Expert Panel (TLEP) WSDL Specifications. While there is a use case for Direct in other medical arenas, there is a strong argument against using Direct in the immunization space, but rather continue to use SOAP web services for immunizations. Direct was considered for an IIS use case by the CDC TLEP, but because Direct does not support synchronous response, which impedes the long term need for Query/Response to support bi-directional communication, SOAP was selected instead of Direct as the recommended transport layer. The December 2013 Quarterly IIS MU Survey referred to above also provides data on transport. Forty-one (41) of fifty-five (55) respondents are engaged in SOAP as their Transport. Of those forty-one, thirty-five (35) are in production, and twenty-three (23) of the forty-one are working directly with the CDC WSDL. By supporting web services as a Stage 3 standard, the Task Force will support better positioning for both IIS and EHRs for Query/Response. We understand that the committee is strongly recommending the use of Direct, but this is only after the committee concluded that Query/Response was not something IIS could support in the time frame necessary for Stage 3. Since we do believe that Query/Response is feasible in this time frame, we maintain (for the reasons stated) that web services continues to be the right strategy and investment for supporting both data submission and query/response between an EHR and an IIS.

§ 170.315(h)(4) (Transmit – Applicability Statement for Secure Health Transport &Delivery Notification in Direct)

MU Objective N/A
2015 Edition EHR Certification Criterion (4) Transmit – Applicability Statement for Secure Health Transport &Delivery Notification in Direct Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(d).

Preamble FR Citation: 79 FR10914	**Specific questions in preamble?***No*

Public Comment Field:

AIRA's comments for 170.315(h)(1), 170.315(h)(2), 170.315(h)(3) and 170.315(h)(4) are the same. On the matter of transport of immunization data, AIRA reiterates our long standing support for SOAP web services, specifically the CDC Transport Layer Expert Panel (TLEP) WSDL Specifications. While there is a use case for Direct in other medical arenas, there is a strong argument against using Direct in the immunization space, but rather continue to use SOAP web services for immunizations. Direct was considered for an IIS use case by the CDC TLEP, but because Direct does not support synchronous response, which impedes the long term need for Query/Response to support bi-directional communication, SOAP was selected instead of Direct as the recommended transport layer. The December 2013 Quarterly IIS MU Survey referred to above also provides data on transport. Forty-one (41) of fifty-five (55) respondents are engaged in SOAP as their Transport. Of those forty-one, thirty-five (35) are in production, and twenty-three (23) of the forty-one are working directly with the CDC WSDL. By supporting web services as a Stage 3 standard, the Task Force will support better positioning for both IIS and EHRs for Query/Response. We understand that the committee is strongly recommending the use of Direct, but this is only after the committee concluded that Query/Response was not something IIS could support in the time frame necessary for Stage 3. Since we do believe that Query/Response is feasible in this time frame, we maintain (for the reasons stated) that web services continues to be the right strategy and investment for supporting both data submission and query/response between an EHR and an IIS.

C. Other Topics for Consideration for the 2017 Edition Certification Criteria Rulemaking

Blue Button +	
Preamble FR Citation: 79 FR10927	**Specific questions in preamble?***Yes*

Public Comment Field:

AIRA expresses general support for the Blue Button + concept, and asks to participate in workgroups as they explore this issue. AIRA would also like to offer assistance in exploring use cases for immunization and fine tuning Blue Button + to meet our specific needs.

2D Barcoding	
Preamble FR Citation: 79 FR10928	**Specific questions in preamble?***Yes*

Public Comment Field:

AIRA supports a 2017 Edition certification criterion requiring EHR systems to consume 2D barcodes for immunization messaging, and advocates that 2-D barcoding should support messaging of NDC and CVX codes. While there is a location in the RXA segment for a barcode string, this is still optional. Having the EHR translate and message the NDC/CVX codes builds on existing functionality. And with a prospective look forward, 2D barcoding could facilitate more accurate immunization inventory management. For these reasons, AIRA is in support of this proposed requirement.

Additional Patient Data Collection	
Preamble FR Citation: 79 FR10922	**Specific questions in preamble?***Yes*

Public Comment Field:

While section 170.315(b)(1) addresses data requirements for matching to support Transitions of Care, there are other needs within MU for appropriate and accurate matching. Public health data submission (immunizations, ELR, Syndromic Surveillance, Cancer Registries and Other Registries) also require accurate patient records to support matching. AIRA recommends the following additional data elements which would be useful if captured by an EHR and included for matching purposes:

- *Previous first name*
- *Previous/maiden last name*
- *Historical address (street address, city, state, zip code)*
- *Historical phone number*
- *External registry ID (e.g., the ID provided by an Immunization Information System for that patient)*
- *Multiple birth indicator and birth order*

Duplicate Patient Records	
Preamble FR Citation: 79 FR10928	**Specific questions in preamble?***Yes*

Public Comment Field:

AIRA supports the concept of improved capability within EHR systems to prevent and identify duplicate patient records, including support for enhanced capabilities in identifying potential duplicates at the time a new record is established in the EHR [see §170.315(b)(1) Transitions of care response above], and administrator-accessible tools and reports to identify potential duplicates that may already be in the EHR database AIRA also supports the concept of a uniform test deck or process for validating a system's capacity for identifying and resolving duplicate records.

Disaster Preparedness	
Preamble FR Citation:79 FR10928	**Specific questions in preamble?***Yes*

Public Comment Field:

AIRA offers its experience in supporting disaster recovery for the immunization component. AIRA and broader PH want to continue to coordinate development of best practices for response in disaster preparedness.