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

AIRA Responses to CMS Stage 2 Meaningful Use NPRM

AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

May 6, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–0044–P
P.O. Box 8013
Baltimore, MD 21244–8013

Submitted electronically at http://www.regulations.gov

Dear Centers for Medicare & Medicaid Services:

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 efforts succeed in furthering the goal of exchanging data between EHRs and IIS.

AIRA's response to the Stage 2 Proposed rules is below. Each table contains the proposed rules and AIRA proposed retentions or changes. Comments/rationale for AIRA's proposed changes are below the tables.

1. Movement from Menu to Core (Objective 15 (i), Measure 15(ii))

Citation	Proposal	AIRA Proposed Retention or Change
Proposed Objective, Pages 119-123 of CMS-0044-P	Proposed Objective: *Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.* *This objective is in the Stage 2 core set for EPs, EHs, and CAHs.*	AIRA strongly supports moving this objective from menu to core AIRA supports the phrase "except where prohibited by law" and suggests the addition of "and in accordance with applicable law and practice." The revised phrase would read "*except where prohibited by law and in accordance with applicable law and practice*." AIRA recommends use of the term "*immunization information systems*" exclusively in place of "immunization registries or immunization information systems."

Proposed Measure, Pages 119-123 of CMS-0044-P	Proposed Measure: *Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.* *Unlike in Stage 1, a failed submission would not meet the objective. An eligible provider must either have successful ongoing submission or meet exclusion criteria.*	In order to promote successful data exchange, AIRA strongly recommends that this measure be amended to: "*Successful ongoing submission, including all aspects of validating incoming messages (testing for format, content, and any detailed data quality tests used by the IIS) of electronic immunization data from Certified EHR Technology to an immunization information system for the entire EHR reporting period. Measurement criteria for ongoing submission will be determined locally.* *Unlike in Stage 1, a **single** failed submission would not meet the objective. An eligible provider must either have successful ongoing submission or meet exclusion criteria*." AIRA further recommends that "*immunization data*" be defined as all immunization data about the patient that is stored in the EHR. This would include immunizations that were administered by the provider, as well as historical/legacy immunizations stored on the patient's record.

AIRA Comments

I. AIRA strongly supports moving the immunization components of Meaningful Use (MU) Stage 2 from Menu to Core. The majority of our community are ready to participate or will be shortly. We do not believe that this change will place an undue burden on EPs and EHs, as feedback from providers who have been on-boarded during Stage 1 has been overwhelmingly positive, and we believe that it can only benefit providers and hospitals to expand the MU requirements for HL7 integration to all immunizing providers and hospitals. Although bi-directional communication is not required for Stage 2, we are encouraged by the indication in the NPRM that it is likely to be required in Stage 3. Ensuring that EHRs have implemented production-quality, unidirectional communication for all immunizing providers is a logical precursor to bi-directional communication.

II. AIRA supports the phrase "*except where prohibited by law*" and suggests the addition of "and in accordance with applicable law and practice. Adding "…*prohibited by law*" makes clear that any prohibitions must be statutory in nature (we believe "by law" is inclusive of tribal codes and statutes) and not only based on Business Associate or other data sharing agreements or organizational policies. Continuing the wording from Stage 1, "according to applicable law and practice" is necessary because state disclosure laws vary, and IIS practice and user agreements are based on state and federal law.

III. AIRA supports clarifying the definition of "*ongoing submission*" to include all aspects of validating incoming HL7 immunization messages: testing for format, testing for content, and any detailed data quality tests that the IIS normally uses when onboarding providers' electronic data. Providers should have continued forward progress throughout the EHR reporting period. This definition clarification is critical to allow for the data quality review process that is an essential element of onboarding. While AIRA is committed to the concept of "*ongoing submission*" as a core measure, to fulfill their missions IIS must above all maintain high data quality, which cannot be sacrificed to facilitate provider attestation for MU Stage 2. This onboarding, or implementation process can take

anywhere from one to six months, and includes many steps, such as setting up test accounts, getting confidentiality agreements signed, testing for required field inclusion, error message return management, data quality review, and more. Clarifying the definitely of "*ongoing submission*" to include all aspects of validating incoming HL7 immunization messages would allow more of a buffer for IIS to be ready for October 2013/January 2014. Initial test submissions could begin on those dates and as long as the provider actively works through the entire process, then they are meeting "*ongoing submission*."

IV. AIRA supports clarifying the definition of a "*failed submission*" to be failure to meet the suggested revised definition, i.e. failure to meet the local measurement criteria for "*ongoing submission*" that includes all aspects of validating incoming HL7 immunization messages.

V. IIS need to have complete immunization histories in order to provide accurate and reliable decision support to providers. . Sending only administered doses will prevent IIS from having a complete picture of the patient's immunization status. All immunizations are needed to provide vaccine forecasting support for the provider; incomplete histories will affect the provider's immunization rates, as well as public health's ability to monitor community, county and statewide immunization rates and vaccine uptake.

2. Transport Layer (CMS and ONC NPRMs)

Citation	Proposal	AIRA Proposed Retention or Change
Page 120 of CMS-0044-P Page 33, CMS-0044-P Page 84 of ONC EHR certification criteria	*An eligible provider is required to utilize the transport method or methods supported by the public health agency in order to achieve meaningful use.* State Flexibility for Stage 2 of Meaningful Use… *…In addition, whether moved to the core or left in the menu, States may also specify the means of transmission of the data or otherwise change the public health measure, as long as it does not require EHR functionality above and beyond that which is included in the ONC EHR certification criteria as finalized for Stage 2 of meaningful use.* *For the certification criterion proposed at § 170.314(f)(2), we have stated the "transmission capability" as the capability to electronically create immunization information for electronic transmission in accordance with the applicable standards and implementation specifications. We clarify that this criterion focuses on the capability of EHR technology to properly create for transmission immunization information in accordance with the applicable standards and implementation specifications. The criterion does not address the ability to query and evaluate immunization history from the immunizations information systems (IIS) to determine a patient's vaccination need, nor does it address the specific connectivity requirements that an EP, EH, or CAH would need to establish or meet to successfully transmit immunization information, as such requirements are likely to vary from State to State and are outside the scope of certification.*	AIRA supports the language on P. 120 that eligible providers are required to use the transport method or methods supported by the PHA. Many IIS have successful on-going submissions with providers using a variety of tools. We support the continuing usage of the existing transport protocols for Stage 2. AIRA requests clarification on inconsistencies between CMS-0044-P Page 120, CMS-0044-P Page 33, and Page 84 of ONC EHR certification criteria.

P. 157 of ONC EHR certification criteria	*The Secretary adopts the following transport standards:* *(a) Directed exchange. (1) Standard. Applicability Statement for Secure Health Transport* *(incorporated by reference in § 170.299).* *(2) Standard. External Data Representation and Cross-Enterprise Document Media* *Interchange for Direct Messaging (incorporated by reference in § 170.299).* *(3) Standard. Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements* *Traceability Matrix (RTM) version 1.0 (incorporated by reference in § 170.299).* *(b) [Reserved]*	AIRA proposes that ONC require EHR's be certified in SOAP web services as well as Direct. Nineteen state or regional IIS have successful SOAP implementations now, another nineteen are planning implementation in the next 12 months, and more are planned after that. For immunization submissions, AIRA recommends that the SOAP web services requirements include the CDC's Transport Layer Expert Panel WSDL Specifications as these specifications are already used by IIS and meet the EHR to IIS use case better than the RTM version. Here is the link to the CDC's Transport Layer Expert Panel WSDL: **http://www.cdc.gov/vaccines/programs/iis/downloads/transport-specification.pdf**

AIRA Comments:

I. AIRA requests clarification on the statement which explains that states can"*…specify the means of transmission of the data…as long as it does not require EHR functionality above and beyond that which is included in the ONC EHR certification criteria.*"

II. AIRA is concerned that this is inconsistent with the statement on Page 120 that the eligible provider is required to use the transport methods supported by the PHA. We are concerned that existing transports would not be allowed. We are also concerned that providers would seek exemption of sending to PHA if their EHR was not certified with the PHA transport.

III. We believe that the intent of CMS and ONC is for providers to use the transport methods supported by the PHA, as there is a statement in the ONC EHR certification document that says "*The criterion…nor does it address the specific connectivity requirements that an EP, EH, or CAH would need to establish or meet to successfully transmit immunization information, as such requirements are likely to vary from State to State and are outside the scope of certification.*"
Thus, AIRA reiterates our support of allowing PHA to use their existing transport methods. We further request that CMS and ONC elaborate that providers cannot claim exclusion to reporting to IIS based upon the transport method. Failure to meet transport was not an exclusion criterion for Stage 1; it should not be an exclusion criterion for Stage 2. Direct was considered for an IIS use case by the CDC Transport Layer Expert Panel (TLEP). 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. Here is a

link to this project: http://www.cdc.gov/vaccines/programs/iis/downloads/ehr-interop-trans-layer-tech-recs.pdf

3. Attestation

Citation	Proposal	AIRA Proposed Retention or Change
Attestation, Page 120 of CMS-0044-P	The expectation is that…public health agencies (PHA) will establish a process where PHAs will be able to provide letters affirming that the EP, EH or CAH was able to submit the relevant public health data to the PHA.	AIRA proposes changing this requirement from PHA having to supply a "letter" to PHA providing "evidence" of ongoing submission, which could include an email, HL7 ACK message, screen shot of completed submission in IIS, etc., at the discretion of the IIS.

AIRA Comments:

I. A requirement to provide letters would place undue burden on IIS that would be a drain on resources and take focus away from supporting ongoing submission. Amending this to requirement to the provision of evidence maintains the spirit of the requirement, and reduces the burden on the IIS.

4. Exclusion Criteria for Immunization Submissions

Citation	Proposal	AIRA Proposed Retention or Change
Page 123 of CMS-0044-P	*"Exclusions: Any EP, eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) the EP, eligible hospital or CAH does not administer any of the immunizations to any of the populations for which data is collected by the jurisdiction's immunization registry or immunization information system during the EHR reporting period; (2) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of receiving electronic immunization data in the specific for Certified EHR Technology at the start of their EHR reporting period; or (3) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for Certified EHR Technology at*	AIRA requests clarification on Items 2 and 3 in this proposal. It appears there is a word missing in Item 2, "*…in the specific for Certified EHR Technology…*" Should there be a word after "*specific*"? Also, Item 3 allows a provider to claim exclusion if the state IIS cannot accept the specific standards required for EHR Technology. If AIRA assumes that Item 2 is referring to transport or transmission of the data and Item 3 is referring to the standards required, then we reiterate our position that eligible providers should be required to use the transport method or methods supported by the PHA. We further request that CMS and ONC elaborate that providers cannot claim exclusion to reporting to IIS based upon the transport method. Failure to meet transport was not an exclusion criterion for Stage 1; it should not be an exclusion criterion for Stage 2.

	the start of their EHR reporting period. For the second and third scenarios, there is no exclusion if an entity designated by the immunization registry can receive electronic immunization data submissions. For example, if the immunization registry cannot accept the data directly or in the version of HL7 used by the provider's Certified EHR Technology, but has designated a Health Information Exchange to do so on their behalf, the provider could not claim the 2nd or 3rd exclusions previously noted."	

AIRA Comments

I. Items 2 and 3 seem to be related; 2 is saying the IIS isn't capable of receiving data in the specific {transmission, transport} for certified EHR technology, and 3 is saying the IIS isn't capable of accepting the specific standards required for certified EHR technology. Is this yet another contradiction to the, *"providers are required to use the transport methods supported by the PHA*"? If Item 2 really means specific transport, then they are referencing the EHR criteria again as the benchmark (Direct, SOAP optional). If Item 3 really means the standard of HL7, then if the state can't receive 2.5.1 (or 2.3.1 if we can get it in the rule), the provider can claim exclusion.

5. Bi-directional Data Exchange

Citation	Proposal	AIRA Proposed Retention or Change
Page 122 of CMS-0044-P	*"Stage 3 is likely to enhance this functionality to permit clinicians to view the entire immunization registry/immunization information system record and support bi-directional information exchange."*	AIRA strongly recommends that CMS use the final rules for Stage 2 to signal the likelihood of bi-directional exchange between certified EHR systems and IIS in Stage 3, either as a menu or Core objective. The real value of an IIS to providers and hospitals is in receiving the IIS's patient immunization history and vaccine decision support information. This also supports the public health goal of improving immunization practice population coverage levels. The IIS community, in partnership with EHR vendors, has selected SOAP web services as the transport mechanism best suited to support such bi-directional exchange, and is moving to rapidly adopt this standard across the country.

6. HIE as Data Intermediaries

Citation	Proposal	AIRA Proposed Retention or Change
Page 120 of CMS-0044-P	Language allows HIEs as intermediaries to transport data to a PHA. "*we clarify that…HIE organizations, if serving on behalf of the public health agency to simply transport the data, but not transforming content or message format (for example, HL7 format), are acceptable for the demonstration of meaningful use. Alternatively, if the intermediary is serving as an extension of the EP, eligible hospital or CAH's Certified EHR Technology and performing capabilities for which certification is required (for example, transforming the data into the required standard), then that functionality must be certified in accordance with the certification program established by ONC.*"	If used to transform data to meet standards, then AIRA supports the requirement that the HIE be certified against 2014 certification standards.

AIRA Comments

I. PHAs receiving data through an HIE intermediary must know that the functionality used to transform data to meet Meaningful Use standards has been certified by an ONC-ATCB. This is especially relevant given the proposed requirement for PHAs to provide affirmations letters as part of the attestation process and audits.

7. Submitting to a "specialized registry"

Citation	Proposal	AIRA Proposed Retention or Change
Page 134 of CMS-0044-P	Proposed EP Objective: "*Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice."*	AIRA suggests that language be amended to "*a registry (other than a cancer registry or an immunization information system)...*"

AIRA Comments

I. Many specialized registries exist both within PHAs and other entities. CMS' intent to provide flexibility for EPs based on their scope of practice is sensible, and also allows for natural variability in what specialized registries exist across PHAs or other authorized entities. Non-governmental entities could include universities, health plans, provider associations, research groups, etc. Examples of specialized registries include diabetes, lead, Sickle cell, joint replacement and BMI. We assume that

"*applicable law and practice*" covers whether the specific cases reported include named or unnamed data.

We sincerely appreciate the opportunity to provide comments on the Proposed Stage 2 and Stage 3 criteria and hope that our comments are helpful. If you have any questions regarding our comments or need additional information, please contact Emily Emerson at Emily.Emerson@state.mn.us.

Sincerely,

Loretta A. Santilli, President
AIRA

Emily Emerson, Immediate Past President
AIRA

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AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

AIRA Responses to ONC 2014 Edition EHR Standards and Certification Criteria Proposed Rule

AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

May 6, 2012

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: 2014 Edition EHR Standards and Certification Criteria Proposed Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue SW
Washington, D.C. 20201

Re: RIN 0991-AB82
Submitted electronically at http://www.regulations.gov

Dear Office of the National Coordinator for Health IT:

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 efforts and EHR Standards and Certification Criteria succeed in furthering the goal of exchanging data between EHRs and IIS, and AIRA is extremely interested in working with ONC and NIST on the test case for IIS submission/certification

AIRA's response to the 2014 Edition EHR Standards and Certification Criteria is below. Each table contains the proposed rules and AIRA proposed retentions or changes. Comments/rationale for AIRA's proposed changes are below the tables.

1. HL7 2.5.1 Standard (ONC Certification Document)

Citation	Proposal	AIRA Proposed Retention or Change
Page 83 of ONC EHR certification criteria	Content Standards/Specifications: HL7 2.5.1 and Implementation Guide for Immunization Messaging Release 1.3	AIRA supports the decision to require HL7 2.5.1 for Stage 2, and we strongly support that providers already submitting using the 2.3.1 standard or those that attest to Stage 1 using 2.3.1 before October 1, 2013, should be allowed to meet Stage 2 using this standard. All new, previously un-attested connections to IIS following October 1, 2013, need to be made using HL7 2.5.1. While the current implementation guide is release 1.3, a newer release is expected for later this year. We recommend that ONC reference the most recent version in the final rules, as implementation guides are not static documents; they are refined with use and experience. The IIS community is

		committed to reducing jurisdictional variability in the requirements for immunization messages, and making technical corrections to the guide as needed. Pointing to the most recent version as published by CDC reflects the reality of ever-evolving implementations guides. AIRA strongly recommends the inclusion of the National Vaccine Advisory Committee (NVAC) approved Immunization Information System Core Data Elements as required elements in the final Standards. The list of core data elements is being revised and the updated list should be published before the beginning of Stage 2. The core data elements support the public health goals supported by IIS. AIRA supports the continued usage of CVX (vaccine codes) as the dataset standards for immunizations, and we also encourage ONC to add MVX (manufacturer codes) to the standard as well. The combination of CVX and MVX allow a specific vaccine to be identified. This is important to support forecasting of next dose due.

AIRA Comments:

I. Allowing providers already submitting using the 2.3.1 standard to meet Stage 2 will allow the many successful 2.3.1 exchanges occurring be able to continue without adding undue burden to IIS, providers or EHR vendors. By forcing just one standard, early adopters of HL7 and providers who met Stage 1 early will face the most burdens. Allowing the two standards until the beginning of Stage 3, one for existing exchanges and one for new exchanges, will alleviate the rush for both providers and IIS to convert all existing exchanges to 2.5.1. by the beginning of the Stage 2 reporting period.

II. Including core data elements in requirements Standard is critical. Meaningful Use Stage 1 required EHR vendors to support 2.3.1 IG standards, but NVAC core data elements were not called out. EHRs are not capturing the IIS required fields and NIST test cases do not mirror all required data elements creating confusion and frustration for EHR vendors and IIS. AIRA would be happy to assist in ensuring that the required data elements are included in the testing and certification process.

III. Accurate identification of vaccines is crucial for several important functions supported by IIS. At the same time the codes need to accommodate the situation where a specific formulation of a vaccine is not known (record from an immunization card). CVX and MVX were designed to meet this need.

2. Transport Layer (CMS and ONC NPRMs)

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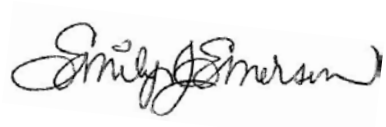
III. We believe that the intent of CMS and ONC is for providers to use the transport methods supported by the PHA, as there is a statement in the ONC EHR certification document that says "*The criterion…nor does it address the specific connectivity requirements that an EP, EH, or CAH would need to establish or meet to successfully transmit immunization information, as such requirements are likely to vary from State to State and are outside the scope of certification.*"
Thus, AIRA reiterates our support of allowing PHA to use their existing transport methods. We further request that CMS and ONC elaborate that providers cannot claim exclusion to reporting to IIS based upon the transport method. Failure to meet transport was not an exclusion criterion for Stage 1; it should not be an exclusion criterion for Stage 2. Direct was considered for an IIS use case by the CDC Transport Layer Expert Panel (TLEP). 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. Here is a link to this project: http://www.cdc.gov/vaccines/programs/iis/downloads/ehr-interop-trans-layer-tech-recs.pdf. Having EHR systems certified in SOAP for stage 2, as recommended by the TLEP, will enable bi-directional exchange for the many EPs and EHs who want it *now*.

We sincerely appreciate the opportunity to provide comments on the Proposed Stage 2 and Stage 3 criteria and hope that our comments are helpful. If you have any questions regarding our comments or need additional information, please contact Emily Emerson at Emily.Emerson@state.mn.us.

Sincerely,



Loretta A. Santilli, President

AIRA

Emily Emerson, Immediate Past President

AIRA