



May 2, 2014

Department of Health and Human Services  
Office of the National Coordinator for Health Information Technology  
Attention: 2015 Edition EHR Certification Criteria Proposed Rule  
Hubert Humphrey Building  
200 Independence Avenue, SW, Suite 729D  
Washington, DC 20201  
Submitted electronically at: <http://www.regulations.gov/#!submitComment;D=HHS-OS-2014-0002-0001>

Dear Mr. Posnack:

The Association of Immunization Managers (AIM) is a membership association representing the 64 federally-funded state, local and territorial immunization programs.

AIM comments are contained in the public comment template below. AIM also supports the comments submitted by the American Immunization Registry Association (AIRA). AIRA promotes the development and implementation of immunization information systems (IIS) and represents among others, the public health immunization systems of AIM members.

Public health immunization information systems have a history of exchanging data with electronic health record (EHR) systems, schools, health plans and other public organizations. Therefore, we have a strong interest in efforts that further the goal of data exchange between EHRs and IIS.

We sincerely appreciate the opportunity to provide comments on the Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements. If you have any questions regarding our comments or need additional information, please contact Claire Hannan at [channan@immunizationmanagers.org](mailto:channan@immunizationmanagers.org)

Sincerely,

Handwritten signature of Claire Hannan in cursive.

Claire Hannan, MPH  
Executive Director

Handwritten signature of Molly Howell in cursive.

Molly Howell, MPH  
Chair

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

**§ 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 FR 10907

**Specific questions in preamble?** Yes

**Public Comment Field:**

The NPRM seeks comments on whether there should be a move to using NDC codes for vaccines to replace CVX.

AIM supports the use of CVX codes for immunization. AIM recommends that use of National Drug Codes (NDC) be optional and that CVX codes be maintained. Many IIS haven't yet transitioned to NDC. Transitioning to the use of NDC would require a significant effort for IIS. The use of NDC would also require significant maintenance of effort because the NDC change annually for some vaccines such as influenza vaccines. There could be future benefit in using NDC codes but immunization information systems are not ready for this yet. NDC may be the standard down the road and there are ways to link inventory management to NDC codes.

**AIM COMMENTS ON THE VOLUNTARY 2015 EDITION ELECTRONIC HEALTH RECORD (EHR) CERTIFICATION  
CRITERIA; INTEROPERABILITY UPDATES AND REGULATORY IMPROVEMENT**

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

**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) 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(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 FR 10908

Specific questions in preamble? *No*

### Public Comment Field:

ONC seeks public comment on the maturity of bi-directional 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. ONC has received stakeholder comments that the immunization registry community is moving toward, but has not yet developed, fully mature standards for bidirectional data exchange that include immunization forecasting/clinical decision support (CDS).

AIM supports bi-directional exchange. Many IIS are exchanging data bi-directionally, meaning that an EHR queries an IIS, and the IIS returns immunization histories and the patient forecast to the EHR for display within the EHR. Data from the Quarterly IIS MU survey administered by CDC show that 22 IIS are engaged in some level of query/response efforts as of December 2013. Not all IIS are capable of exchanging data bi-directionally (query/response) with EHR systems for several reasons such as local law or policy that prevents the exchange of data, or a lack of resources to upgrade current systems to allow this type of exchange. However, we do believe that bi-directional data exchange is a mature standard.

## § 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 FR 10908

Specific questions in preamble? *Yes*

### Public Comment Field:

The NPRM proposes to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version. AIM supports this proposal as IIS continue to progress beyond current criterion in anticipation of Stage 3. AIM supports the adoption of the 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.

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

### 2D Barcoding

Preamble FR Citation: 79 FR 10928

Specific questions in preamble? Yes

#### Public Comment Field:

ONC solicits comment on whether to propose a 2017 Edition certification criterion requiring EHR systems to consume 2D barcodes and for what functions (e.g., vaccine administration, medication administration).

Two D bar codes are used to identify vaccine products at the vial and packaging level and AIM supports intent. AIM supports the use of 2D barcodes for vaccine ordering, administration, and management. Inclusion of lot number and vaccine expiration date in the bar code label increase the accuracy of vaccine data collection, improve the ability of public health agencies and providers to respond to vaccine recalls, and expedite response and reporting of potential vaccine adverse events. These improvements will continue the advancement of public health and medical information technology toward the goal of automated data exchange between electronic medical records, provider vaccine inventory and ordering, and immunization information systems.

AIM acknowledges the future benefits of 2D barcoding and supports a 2017 Edition certification criterion requiring EHR systems to consume 2D barcodes for immunization messaging. AIM advocates that 2D barcoding support the messaging of NDC and CVX codes.

AIM also recommends that the vaccine funding source (private vs. public) be a required field in EHRs for inventory management. Without EHRs designation of the funding source, public health agencies don't know if the dose should be decremented from the private or public inventory. For public health, this issue has significantly affected some CDC funded immunization programs in their use of IIS to track the borrowing and return of vaccine between VFC and private inventory.

AIM also supports inclusion of the Vaccine Information Statement (VIS) on the 2D bar coding, recognizing that this issue becomes more complex with combination vaccines.

## Disaster Preparedness

Preamble FR Citation: 79 FR 10928

Specific questions in preamble? Yes

### Public Comment Field:

This portion of the rule is related to how EHR technology can be used to enhance emergency preparedness and assist in response. AIM comments respond to the following two questions.

- Whether there are particular capabilities or standards we should consider as part of EHR certification that would better assist providers to track and identify patients and victims and share basic clinical information quickly across the full continuum of care during everyday emergencies, disasters, and public health emergencies?
- Whether there are any EHR capabilities and certification criteria that we should consider for certification that could improve /expedite how EHR technology is used to report standardized and de-identified patient data to public health and emergency management authorities, in a manner that would allow such authorities the ability to measure, track and trend health system resiliency, stress, preparedness, and recovery.

AIM suggests the ability to track event and priority groups for future public health events (such as a pandemic influenza outbreak), be added as a standard for inclusion in EHR technology. EHR systems need to have rules and standards for collecting and reporting data for vaccination events such as a pandemic or vaccine shortage and for capture of priority groups during a vaccination event. In terms of priority groups, there could be a standard, generic list – most of the high risk groups remain the same – that is pre-programmed.

Certification should require that EHRs have a way to identify high risk patients with the understanding that those high priority groups can change, based on the situation. (This may have to be determined based on some recorded clinical information – to decide if the person belongs to this high risk group or not. We envision that there would be some type of drop down list that might indicate certain health conditions.).

Efforts should be undertaken now to encourage EHR vendors to build a mechanism to record the funding source for vaccination events and priority groups into their systems. Public health has a strong need for the collection of these data and if these fields do not exist, future collection of this information may be compromised.

AIM also recommends inclusion of fields for the tracking of antivirals or adjuvants associated with vaccines, although these can be tracked with the CVX codes in an emergency situation.