January 14, 2013

Department of Heath and Human Services
Office of the National Coordinator for Health Information Technology

RE: Health Information Technology (HIT) Policy Committee Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHR)
Attention: HHS OS-2012-0007-0001

Dear Health Information Technology Policy Committee Members:

The Association of Immunization Managers (AIM) is a membership association representing the 64 federally-funded state, local and territorial immunization programs. AIM members are the managers of these programs receiving Section 317 immunization grants to ensure high immunization coverage rates in the population.

AIM strongly supports the development of immunization information systems (IIS) and their linkage with EHRs. AIM is pleased to provide comments on the draft recommendations pertaining to immunization for stage 3 of meaningful use.

**SGRP 113**

**Objective:** Use clinical decision support to improve performance on high priority health conditions

**Measure:**
1. Implement 15 clinical decision support interventions or guidance related to five or more clinical quality measures that are presented at a relevant point in patient care for the entire EHR reporting period. The 15 CDS interventions should include one or more interventions in each of the following areas, as applicable to the EP’s specialty:
   - Preventive care (including immunizations)
   - Chronic disease management, including hypertension* (e.g., diabetes, coronary artery disease)
   - Appropriateness of lab and radiology orders
   - Advanced medication-related decision support** (e.g., renal drug dosing)
2. The EP, eligible hospital, or CAH has enabled the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

**AIM response:**

AIM supports this measure and would also like to reference our comments under 401A and 401B about the capacity of immunization information systems (IIS) to provide clinical decision support via EHRs.
Clinical decision support (CDS) has different meaning for immunization than in other aspects of health care. Immunization looks at clinical decision support from a unique perspective that entails reminder recalls and adverse events reporting. Clinical decision support is used to determine the recommended vaccines for a patient and is based on factors that include the age of the client, the age at vaccine administration, the number of doses, dosing intervals, precautions, and contraindications.

Immunization information systems have a long history of creating, maintaining and updating vaccine recommendations into their forecasting algorithms. IIS forecasting also includes other information critical to vaccine recommendations such as contraindications, history of disease, and substance refusal. A great amount of time is spent on immunization CDS. CDS for immunization requires a unique expertise as there are technical aspects and nuances of each vaccine that need to be understood, including the fluid nature of the recommendations themselves. As a result, IIS forecasting, or the ability to determine when and which vaccines are due to be given, requires ongoing maintenance. Some states allow for flexibility or local variations in the timing of the schedule and this functionality is already supported by IIS.

IIS systems, or registries, have this capability built into them; therefore it is critically important to use registries for the CDS; rather than having EHRs develop their own systems. It is difficult to make these algorithms accurate according to state and local law.

We encourage EHR vendors to utilize the local IIS CDS or a public health CDS web service that is supported by the state/city/county immunization program in the jurisdiction that the provider office resides. We do not believe it is feasible to mandate a single CDS solution for immunization; we believe the proposed recommendation recognizes this reality. We further believe that the Centers for Disease Control and Prevention (CDC) CDS guidelines for IIS clinical decision support Clinical Decision Support for Immunization (CDSI); Logic Specification for ACIP Recommendations, should be referenced as the authority for ensuring the IIS forecasting is correctly coded based upon the ACIP recommendations, and in accordance with applicable law and practice. If an EHR develops its own algorithms for CDS, it must meet the standards set by CDC.

We also suggest that EHR-supported immunization forecast, including contraindications and documented immunity, become a core requirement into the registry CDS.

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**SGRP 401A**

**EP/EH Objective:** Capability to receive a patient’s immunization history supplied by an immunization registry or immunization information system, and to enable healthcare professionals to use structured historical immunization events in the clinical workflow, except where prohibited, and in accordance with applicable law and practice.

**Measure:** Documentation of timely and successful electronic receipt by the Certified EHR technology of vaccine history (including null results) from an immunization registry or immunization information system for 30% of patients who received immunization from EP/EH during the entire EHR reporting period.
Exclusion: EP’s and EH’s that administer no immunizations or jurisdictions where immunization registries/IIS cannot provide electronic immunization histories.

Certification criteria: EHR is able to receive and present a standard set of structured, externally generated, immunization history and capture the act and date of review within the EP/EH practice.

AIM response: The recommendation refers to the ability to absorb the immunization history somewhere in the EHR however the intent of this objective is not clear. Is the issue the ability of the EHR to query an IIS and receive a consolidated, de-duplicated immunization history? If the EHR is just to receive the history from an IIS or immunization registry and use the IIS forecasting algorithm to recommend the next vaccinations, then AIM supports this recommendation. However, if the goal is for the EHR to have its own algorithm, and to be able to run reminder recalls and similar actions, then displaying the information would not be enough. We are assuming the simplest approach, which is for the EHR to be able to query an IIS and receive back consolidated, de-duplicated immunization history.

Proposed for Future Stage under SGRP 401A:
EP/EH Objective: Add submission of vaccine contraindication(s) and reason(s) for substance refusal to the current objective of successful ongoing immunization data submission to registry or immunization information system.

AIM response: AIM supports this recommendation and would be supportive of including it in Stage 3 of meaningful use as most IIS need it now. Many EHRs are already submitting vaccine contraindications, history of disease and substance refusal reasons to an IIS, so we believe this should be an easy addition to the Stage 3 meaningful use recommendations.

SGRP 401B
EP/EH Objective: Capability to receive, generate or access appropriate age-, gender- and immunization history-based recommendations (including immunization events from immunization registries or immunization information systems) as applicable by local or state policy.

Measure: Implement an immunization recommendation system that: 1) establishes baseline recommendations (e.g., Advisory Committee on Immunization Practices), and 2) allows for local/state variations. For 20% of patients receiving an immunization, the EP/EH practice receives the recommendation before giving an immunization.

Exclusion: EPs and EHs that administer no immunizations.

Certification criteria: EHR uses a standard (e.g., national, state and/or local) rule set, plus patient age, gender, and prior immunization history to recommend administration of immunizations; capture the act and date/time of recommendation review.
**AIM Response:**

AIM supports this measure and suggests that the wording “according to CDC standards and ACIP recommendations,” be added before the phrase “as applicable by local or state policy.” While variation occurs, AIM supports CDC’s policy to try to eliminate local variation.

AIM feels it is important to reiterate that IIS have a long history of creating, maintaining and updating vaccine recommendations and forecasting into their systems. A great amount of time is spent on immunization CDS; there is a unique, dedicated expertise required as there are technical aspects and nuances of each vaccine that need to be understood and the fluid nature of the recommendations needs to be monitored and updated on an ongoing basis. The CDC recently published guidelines for CDS for IIS, establishing one authoritative venue for ensuring that IIS forecasting is correctly coded based upon the ACIP recommendations. Some states allow for flexibility or local variations in the schedule; this functionality is already supported by IIS.

We further encourage that EHR vendors utilize the local IIS CDS or a public health CDS web service that is supported by the state/city/county immunization program in the jurisdiction where the provider office resides as consolidated immunization histories are important for forecasting. This would ensure that if the state IIS has the capability and is the authoritative resource for vaccine forecasting, EHRs could take advantage of existing functionality. In states that do not have vaccine forecasting via the IIS, EHRs could call upon a CDS web service. We do not believe it is feasible to mandate a single CDS standard for immunization; we believe the proposed recommendation recognizes this reality.

**New: SGRP 408**

**EH/EP Objective:** Capability to electronically send adverse event reports (e.g., vaccines, devices, EHR, drugs or biologics) to the Federal Drug Administration (FDA) and/or Centers for Disease Control and Prevention (CDC) from the Certified EHR, except where prohibited, and in accordance with applicable law and practice.

**Measure:** Attestation of successful electronic transmission of standardized adverse event reports to the FDA/CDC from the Certified EHR Technology. Total numeric count (null is acceptable) of adverse event reports from the EH/EP submitted electronically during the entire EHR reporting period as authorized, and in accordance with applicable State law and practice.

**Certification criteria:** EHR is able to build and send a standardized adverse event report message to FDA/CDC and maintain an audit of those reports sent to track number of reports sent (Common Format).

**AIM Response:**

If an EHR is reporting adverse events to CDC, it’s important that CDC report that information back to the state and local health departments in a timely fashion and the local jurisdiction can decide what to do with that information.
IEWG 101:

Menu objective: For patients transitioned without a care summary, an individual in the practice should query an outside entity. The intent of this objective is to recognize providers who are proactively querying.

Certification criteria: The EHR must be able to query another entity for outside records and respond to such queries. The outside entity may be another EHR system, a health information exchange, or an entity on the NwHIN Exchange, for example. This query may consist of three transactions:

a) Patient query based on demographics and other available identifiers, as well as the requestor and purpose of request.

b) Query for a document list based for an identified patient.

c) Request a specific set of documents from the returned document list.

When receiving inbound patient query, the EHR must be able to:

a) Tell the querying system whether patient authorization is required to retrieve the patient’s records and where to obtain the authorization language*. (E.g. if authorization is already on file at the record-holding institution it may not be required).

b) At the direction of the record-holding institution, respond with a list of the patient’s releasable documents based on patient’s authorization.

c) At the direction of the record-holding institution, release specific documents with patient’s authorization.

The EHR initiating the query must be able to query an outside entity* for the authorization language to be presented to and signed by the patient or her proxy in order to retrieve the patient’s records. Upon the patient signing the form, the EHR must be able to send, based on the preference of the record-holding institution, either:

1. a copy of the signed form to the entity requesting it,

2. an electronic notification attesting to the collection of the patient’s signature.

*Note: The authorization text may come from the record-holding EHR system, or, at the direction of the patient or the record-holding EHR, could be located in a directory separate from the record-holding EHR system, and so a query for authorization language would need to be directable to the correct endpoint.

AIM Response:

Public health immunization systems have been dealing with this for years and that experience needs to be leveraged. Immunization information systems and registries should be included as a target for some of those queries.

In closing, we offer one final comment. Incentive funding is provided to participating providers but is not offered to public health. As the implementation of meaningful use moves forward, the cost and burden on public health has been rising substantially. Public health is not only supporting the testing and onboarding of physicians, but also developing the capacity and infrastructure to support interoperability between EHRs and IIS. Long-term, permanent incentive funding is needed to support
public health agencies to maintain and develop IIS system. Permanent staff need to be hired to work on the activities associated with implementation.

We appreciate the opportunity to provide comments. If you have any questions or need additional information, please contact me at channan@immunizationmanagers.org.

Sincerely,

Claire Hannan, MPH
Executive Director