AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

May 18, 2015

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

RE: Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3

To Whom It May Concern:

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on CMS's ***Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3.*** As a member organization with more than 250 members from 60 Public Health organizations, 11 businesses and sponsors, and 26 individuals representing Immunization Information System (IIS) programs and partners, these comments represent a broad perspective on federal actions that impact immunization programs across the country, and we are particularly interested in informing standards specifications.

AIRA and the IIS community are pleased to see bidirectional exchange included for Meaningful Use (MU) Stage 3. Based on data reported in response to CDC's IIS Support Branch MU survey, 28 IIS (approximately 52% of reporting systems) currently report to CDC that they have query capabilities in production today using HL7 2.5.1, and 37 (or 70% of reporting systems) had a SOAP/Web Services transport solution in production. By 2018, these numbers are anticipated to encompass the entire IIS community. The inclusion of query for the immunization registry measure in this final stage of meaningful use signals a significant step forward toward efficient clinical decision support at the point of care.

We do have concerns, however, that MU Stage 3 appears to deemphasize IIS reporting by no longer requiring it as a measure, which threatens to interrupt the positive forward momentum for EHR-IIS interoperability that was accelerated by MU Stages 1 and 2. We have some suggestions in our detailed comments presented on the following pages, organized by page number and section within the Proposed Rule. Please contact Rebecca Coyle, AIRA's Executive Director, with any questions: coyler@immregistries.org.

AIRA greatly appreciates the opportunity to comment on CMS standards, and we look forward to supporting our members toward stronger interoperability with our EHR partners.

Sincerely,

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

AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

# Comments on the Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3

**By: AIRA**

| ***Section, Page Number*** | ***Excerpt*** | ***Comment*** |
|---|---|---|
| Summary, Page 16732 | This Stage 3 proposed rule would also change the EHR reporting period so that all providers would report under a full calendar year timeline with a limited exception under the Medicaid EHR Incentive Program for providers demonstrating meaningful use for the first time. | AIRA supports the changes to both the reporting period start and end dates and the duration. We feel this will make it easier to track and communicate with providers when they are required to register and what timeframes they are reporting for.<br>• Calendar year reporting<br>• Full year reporting period<br>• Exception if you are a Medicaid EP or EH demonstrating MU for the first time, then a continuous 90-day period |
| State Flexibility, Page 16740 | (iii) State Flexibility for Stage 3 of Meaningful Use Consistent with our approach under both Stage 1 and 2, we propose to continue to offer states flexibility under the Medicaid EHR Incentive Program in Stage 3 by adding a new provision at § 495.316(d)(2)(iii) subject to the same conditions and standards as the Stage 2 flexibility policy. Under Stage 3, state flexibility would apply only with respect to the public health and clinical data registry reporting objective outlined under section II.A.1.c.(1).(b).(i). of this proposed rule. For Stage 3 of meaningful use, we would continue to allow states to specify the means of transmission of the data and otherwise change the public health agency reporting objective as long as it does not require functionality greater than what is required for Stage 3 and included in the 2015 Edition proposed rule elsewhere | It's not clear if this refers to just measures 4 and 5 or whether it applies to whether other registries such as immunization registries. AIRA would appreciate clarification of the rule to include immunization registries. It is critical that the rule allows states to continue to specify transport options.<br><br>AIRA seeks further clarification on this portion of the rule; does this mean that a state immunization registry could not require data from a partner organization beyond what is required by the CDC Version 1.5 implementation guide? Given that local implementation guides are derived from the nationally specified CDC guide, please clarify that this flexibility from Stage 2 continues into Stage 3. |

AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

| ***Section, Page Number*** | ***Excerpt*** | ***Comment*** |
|---|---|---|
| | in this issue of the Federal Register. | |
| Objective 8, Page 16763 | Proposed Measures: We are proposing a total of six possible measures for this objective. EPs would be required to choose from measures 1 through 5, and would be required to successfully attest to any combination of three measures. Eligible hospitals and CAHs would be required to choose from measures one through six, and would be required to successfully attest to any combination of four measures.<br><br>The purpose of this Stage 3 objective is to further advance communication between providers and PHAs or CDRs, as well as strengthen the capture and transmission of such health information within the care continuum. | The aim of Objective 8 is to "further advance communication between providers and PHAs or CDRs, as well as strengthen the capture and transmission of such health information within the care continuum" while giving health care providers the flexibility to "choose reporting options that align with their practice and that will aid the provider's ability to care for their patient". This flexible approach to selecting measures is in direct contrast to Stage 2 of the program, where Measures 1, 2 and 6 were core objective that health care organizations were required to fulfill**. It seems that this new flexibility could jeopardize existing transmission of public health data by not continuing the required Stage 2 measures.** Existing submitters may choose to implement new measures and discontinue current public health integrations rather than upgrade them to meet Stage 3 standards. For instance, Measure 1 requires significant new capabilities to request, access and display a patient's immunization history and forecast which health care providers may see as an unnecessary implementation burden if other, simpler measures can be met. In this instance, it is possible that the existing vaccination administration integration could be deprioritized within the organization if resources are needed elsewhere and the integration does not help them achieve compliance. Collected data (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6238a5.htm and http://www.cdc.gov/MMWr/preview/mmwrhtml/mm6412a5.htm) clearly show a significant and consistent increase in the submission of electronic public health data attributed to the implementation of EHR incentive programs. To ensure that such gains are not reversed, it would be appropriate to require Measures 1, |

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

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

| ***Section, Page Number*** | ***Excerpt*** | ***Comment*** |
|---|---|---|
| | | 2 and 6 plus 1-2 additional measures of the health care provider's choice.<br><br>AIRA also requests that CMS consider removing Clinical Data Registries (CDR) as part of the public health measure. AIRA's view is that CDRs aren't part of our public health reporting systems and as a result, providers and hospitals shouldn't be able to use them to as part of the public health reporting measure.<br><br>The potential impact of leaving CDRs in the public health measure is that if we fail to keep immunization reporting (and now querying) as mandatory parts of the public health rule for MU3, CDRs could potentially be used to meet all of the public health measures, leaving out the real public health reporting projects that positively impact the health of the full population. |
| Active Engagement, Page 16763 | For Stage 3, we are proposing to remove the prior "ongoing submission" requirement and replace it with an "active engagement" requirement.<br><br>Providers must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure. | AIRA appreciates the distinction between "ongoing submission" and "active engagement", and fully supports this new wording; this will likely make the rule conceptually simpler for EPs trying to meet it.<br><br>We would, however, suggest that Active Engagement include a requirement for providers or EHRs to not only <u>respond</u> to requests for changes, but to ensure that actual progress is made on outstanding issues raised by the public health agency, which would have the authority to determine if an EP/EH/CAH (or its vendor) is being genuinely responsive or not. |
| Active Engagement, Page 16763 | Providers that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period | For immunization registries, where the proposed rule adds functionality that was not present in the Stage 2 rule, it is not clear whether the EP or hospital that registered intent to send to meet Stage 2 would still intend to meet the new measure. Planning for public health agencies would be simplified by clarifying whether an EP or hospital would |

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

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

| *Section, Page Number* | *Excerpt* | *Comment* |
|---|---|---|
| | | still need to register intent at least once with respect to the new requirements. |
| Objective 8, Measure 1 Page 16764 | We propose that to successfully meet the requirements of this measure, bidirectional data exchange between the provider's certified EHR technology and the immunization registry/IIS is required. We understand that many states and local public health jurisdictions are exchanging immunization data bidirectionally with providers, and that the number of states and localities able to support bidirectional exchange continues to increase. In the 2015 Edition proposed rule published by ONC elsewhere in this issue of the Federal Register, the ONC is proposing to adopt a bidirectional exchange standard for reporting to immunization registries/IIS. | AIRA fully supports the inclusion of bidirectional exchange for immunization registry interoperability in MU 3, as this represents **significant** value for providers and patients alike. As mentioned in our introductory letter, over half of IIS report to CDC that they currently have HL7 2.5.1 query functionality live in production, and this number is increasing rapidly as IIS fully adopt HL7 2.5.1 release 1.5. |
| Exclusion for Measure 1, Page 16764 | Exclusion for Measure 1: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period; (2) operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no immunization registry or | As with previous stages of MU, certification tests set a minimal bar for meeting the standard, but should not be considered to represent comprehensive functionality to support nationwide interoperability. AIRA would like to reiterate that EHRs should not be allowed exemptions based on too conservative of an interpretation of the CEHRT definition and test cases.<br><br>Additionally, the language of "immunization information system has declared readiness to receive immunization data" addresses readiness to receive submissions, but does not address readiness to receive and respond to queries, which is now included in this measure. |

AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

1155 F Street, Suite 1050
Washington, D.C. 20004
(202) 552-0208

| *Section, Page Number* | *Excerpt* | *Comment* |
|---|---|---|
| | immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period. | |