



June 18, 2021

Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Health and Human Services Department
7500 Security Boulevard
Baltimore, MD 21244

RE: Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Ms. Brooks-LaSure,

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on the Centers for Medicare and Medicaid Services recently released documents related to proposed changes in the **Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals**. These comments are a compilation of the input of our members which include over 80 organizations representing Public Health Immunization Information Systems (IIS), IIS implementers and vendors, non-profit organizations and partners. Immunization Information Systems interface with a broad range of stakeholders, including providers, pharmacists, schools, child care facilities, health plans and payers, among others.

IIS and our partners are invested in promoting smooth interoperability to ensure complete data capture and broad data use. At the point of clinical care, an IIS provides consolidated immunization records and forecasts to support clinical decisions. At the population level, an IIS provides aggregate data and information on vaccinations for surveillance, program operations and public health action. It is critical that the role of Public Health is recognized as a key part of health IT strategy moving forward.

To that end, we are writing to strongly support the proposed CMS changes to establish new requirements and revise existing requirements for eligible hospitals and critical access hospitals (CAHs) participating in the Medicare Promoting Interoperability Program. Given the growing importance of health information technology, and the key role vaccines are playing in responding to the COVID-19 global pandemic, we believe that Immunization Information Systems (IIS) are a key part of the health care infrastructure. Incentive programs like Meaningful Use (MU) and Promoting Interoperability (PI) have helped to automate IIS reporting and have improved Electronic Health Record (EHR)-IIS interoperability, thus lowering provider burden and increasing the value and broad use of IIS data. The Office of the National Coordinator for Health



Information Technology (ONC) determined that, as a result of MU, the percentage of participating Medicare professionals who vaccinate and report to an IIS increased from 51% in 2011 to 72% in 2014. Among the IIS community, it has been noted that these efforts disproportionately benefited high-volume providers and pediatricians/family practices who vaccinate children. Similar incentive programs may be needed to assist small and midsize providers with establishing EHR-IIS interfaces.

Broader incentive programs may also be needed to facilitate upgrades to existing interfaces to support bidirectional data exchange. We want to ensure that future strategies for health IT continue to support the important role IIS play in consolidating and sharing immunization information. IIS, or immunization registries enable provider access to the most complete, timely and accurate immunization information available. It is important to note that this is not a public health issue, but rather a health care issue; clinical care can and should benefit as much as public health from near real time access to complete and accurate immunization information.

We applaud and fully support the changes cited in the rule to make the immunization reporting measure required rather than optional. As cited in the draft rule under the PROPOSED MODIFICATIONS TO THE REPORTING REQUIREMENTS FOR THE PUBLIC HEALTH AND CLINICAL DATA EXCHANGE OBJECTIVE, this change would provide immediate benefits for understanding coverage rates and identifying areas in need of additional vaccination efforts. It would also improve data quality within immunization information systems and provide greater opportunities for data use.

As highlighted in the proposed rule, these changes would support stronger capture of COVID-19 vaccine, but looking toward sustainability, this change would also support administration, reporting, and data exchange for routine immunizations as well. Routine immunizations have been deferred and/or missed altogether during the pandemic, and this shift to require the immunization reporting measure would support stronger surveillance and awareness of immunization rates for all vaccines. Embedding immunization data exchange throughout public and private health care will help to ensure informed clinical decisions and data driven population health well into the future.

In anticipation of any concerns regarding provider burden, AIRA would like to highlight that the broad availability of immunization data through real-time Electronic Health Record (EHR)-IIS query significantly lowers the burden (and cost) to providers in accessing immunization records and forecasts at the point of care. This functionality to query the IIS from within an EHR and receive back a consolidated record and forecast for immunizations due is currently available to providers in the vast majority of states across the country and is in the process of being



developed in the remaining locations. This accelerated adoption of query functions across EHRs and IIS is due in large part to incentives provided through Meaningful Use (MU)/Promoting Interoperability (PI).

AIRA provides additional suggestions on the specific requests for information outlined in the draft document; these comments are presented on the following pages, organized by section where appropriate.

We greatly appreciate the opportunity to comment on these draft changes, and we enthusiastically support this shift. We look forward to continuing to collaborate with CMS to ensure high-value health IT interoperability with our many partners. Please feel free to contact me with any questions: mbkurilo@immregistries.org.

Sincerely,

Mary Beth Kurilo, MPH, MSW
Senior Director of Health Informatics
American Immunization Registry Association (AIRA)



Comments: Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals, Requests for Comment

Section and page number (where relevant)	Excerpt	Comment
Page 25653 of Federal Register (page 584 of printed version)	<p><i>How could technical approaches utilizing the FHIR® standard enhance existing data flows required under the public health measures?</i></p> <p><i>What are promising FHIR-based approaches to public health reporting use cases that ONC and CMS should explore for potential future consideration as part of the Promoting Interoperability program and the ONC Health IT Certification Program?</i></p>	<p>There is a growing number of public health FHIR Implementation guides (IGs) that have now been balloted and published through HL7, including immunization decision support, birth defects, vital records, and case reporting.</p> <p>Much of the FHIR work happening across the IIS community currently is focused on workflows that supplement existing standards, rather than replacing the broadly adopted V2 with FHIR. AIRA supports this approach. Given the broad level of adoption of V2, quickly moving from V2 to FHIR in the immunization space would not be a productive use of current resources.</p> <p>New immunization interoperability use cases may be able to be addressed with FHIR, as well as challenging areas where V2 is perhaps not the best fit (e.g., inventory decrementing). This would allow the IIS program and vendor community to increase their knowledge and familiarity with FHIR, while a long-term strategy is developed to explore a broader shift to FHIR messaging.</p>





Section and page number (where relevant)	Excerpt	Comment
Page 25653 of Federal Register (page 584 of printed version)	<i>To what degree are PHAs and individual states currently exploring API-based approaches to conducting public health registry reporting? What other factors do stakeholders see as critical factors to adopting FHIR®-based approaches?</i>	<p>A critical issue to explore is the currently limited availability of data through USCDI compliant EHR APIs. Emphasis must be placed in expanding USCDI and the APIs to support data classes and data elements important to PH reporting. It is important to note that the IIS community's preferred transport standard, SOAP/Web Services and the CDC WSDL, is an API, but with V2 rather than FHIR.</p> <p>Any significant changes to interoperability in the immunization community should accommodate the need for long timelines for adoption. Individual IIS have hundreds, if not thousands of data exchange partners they work with, and an internal change may require those interfaces to change; this is significant work, even if the change is positive or more standards-based.</p>
Page 25653 of Federal Register (page 584 of printed version)	<i>What potential policy and program changes in CMS and other HHS programs could reduce health care provider and health IT developer burden related to measures under the Health Information Exchange and the Public Health and Clinical Data Exchange objectives?</i>	<p>AIRA would support two primary changes:</p> <ol style="list-style-type: none">1. Expansion of EHR APIs is critical to accessing the reporting data needed to fully automate Public Health reporting.2. IIS and other public health programs need support to create a system of infrastructure like the Reportable Conditions Knowledge Management System (RCKMS), MedMorph, and the Immunization Gateway that programs can use to more easily achieve interoperability and that reduces the burden on providers contributing to and accessing consolidated population-level data.

