AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

May 31, 2019

Seema Verma
Administrator, Centers for Medicare and Medicaid Services.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1693–P
P.O. Box 8016
Baltimore, MD 21244–8016

RE: **Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicare Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers**

Dear Administrator Verma -

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on The Centers for Medicare and Medicaid's (CMS's) ***Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicare Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers.*** As a member organization with more than 600 members representing 77 Public Health organizations, 12 businesses and sponsors, and 512 individuals from Immunization Information System (IIS) programs and partners, these comments represent a broad perspective on federal actions that affect immunization programs across the country, particularly as they relate to issues that impact the interoperability of immunization records.

As you may know, and as we have commented on in previous rules, immunizations are acknowledged as one of the most effective and life-saving health interventions of modern medicine; CDC states that the vaccinations given to infants and young children in the past 20 years alone will prevent an estimated 322 million illnesses and save 732,000 lives just in the United States.[1] Similarly, an evidence-based systematic review demonstrated IIS capabilities and actions in increasing vaccination rates, contributing heavily to the overall goal of reducing

[1] MMWR, 2014, accessed 5/28/2018: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm

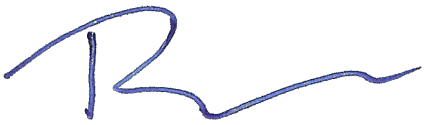
vaccine-preventable disease.[2] IIS are increasingly well-populated, with childhood IIS participation increasing from 90% in 2013 to 94% in 2016, which approaches the Healthy People 2020 objective of ≥95% child IIS participation.[3]

In reading this proposed rule, we have some concerns that the language in the rule is not entirely clear on the role and requirements for public health agencies. In particular, we are concerned that there may be some unintended consequences for local public health agencies that also serve as Medicaid/Medicare care providers. We encourage CMS to clarify where the rule does and does not apply to public health.

We offer some further detailed comments and suggestions presented on the following pages, organized by page number and section within the official Federal Register version of the Proposed Rule published March 4, 2019[4]. Please contact Mary Beth Kurilo, AIRA's Policy and Planning Director, with any questions: mbkurilo@immregistries.org.

AIRA greatly appreciates the opportunity to comment on CMS proposed rules, and we look forward to supporting our members and promoting stronger interoperability with EHRs, to the benefit of providers and patients alike.

Sincerely,



Rebecca Coyle, MSEd, Executive Director

[2] Journal of Public Health Management Practice, 2014, Accessed 5/28/18: https://www.thecommunityguide.org/sites/default/files/publications/vpd-jphpm-evrev-IIS.pdf
[3] MMWR, 2017, accessed 5/31/2018: https://www.cdc.gov/mmwr/volumes/66/wr/mm6643a4.htm
[4] Federal Register, 2019, accessed 4/5/2019: https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and

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Comments on the Medicare and Medicaid Programs; Interoperability and Patient Access Proposed Rules

Section, Page Number	Excerpt	Comment
Pg. 7622	In proposing to require use of specified standards by referencing CFR text at which specific versions of those standards are named, we intend to preclude regulated entities from implementing API technology using alternative technical standards to those ONC proposes for HHS adoption at 45 CFR 170.215, including but not limited to proprietary standards and other standards not widely used to exchange electronic health information in the U.S. health system. We further intend to preclude entities from using earlier versions of the technical standards adopted at 45 CFR 170.215.	We request that the final rule clarify that a statement such as this doesn't prevent vendors and implementers from using existing standards (such as HL7 v2.5.1 Release 1.5 for immunization data exchange). We suggest updating the text to indicate this preclusion only applies to fulfilling the requirements of the rule and is not a general prohibition against using other standards.

Section, Page Number	Excerpt	Comment
Pg. 7623	First, we propose in section III.C.2.b. of this proposed rule to require compliance with the ONC-proposed regulations regarding the content and vocabulary standard at 45 CFR 170.213 as applicable to the data type or data element. This is the USCDI Version 1 set of data classes that can be supported by commonly used standards, and establishes a minimum set of data classes that would be required to be interoperable nationwide.2	We encourage CMS and ONC to consider the CDC endorsed data elements[5] for immunization in reference to the immunization data exchange use case, as well as the AIRA Functional Guide volume that provides more operational detail on the CDC endorsed data elements.[6]
Pg. 7634	For state agencies managing Medicaid or CHIP FFS programs, such data must be included through the API under our proposal only if the state manages clinical data.	We request that the final rule clarify whether or not the presence of a state IIS impacts the requirement to make immunization data available via the API.

[5] CDC website, accessed 4/10/2019: https://www.cdc.gov/vaccines/programs/iis/core-data-elements.html

[6] AIRA Repository, accessed 4/10/2019: https://repository.immregistries.org/resource/iis-functional-guide/

Section, Page Number	Excerpt	Comment
Pgs. 7656-7	In conjunction with ONC, we are posing a request for information regarding how CMS could leverage our program authority to improve patient identification to facilitate improved patient safety, enable better care coordination, and advance interoperability.	Public health has significant experience over a long period of time in patient matching strategies for records collected from diverse clinical locations. We would welcome the opportunity to advise on these topics; please reach out to AIRA directly and we would be happy to connect you with subject matter experts across our community. In addition, the following observations and suggestions are offered from our members in response to select RFI questions:

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Section, Page Number	Excerpt	Comment
Patient Matching RFI, Pgs. 7656-7	Question 1) Should CMS require Medicare FFS, MA Plans, Medicaid FFS, Medicaid managed care plans (MCOs, PIHPs, and PAHPs), CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs (not including SADP issuers), use a patient matching algorithm with a proven success rate of a certain percentage where the algorithm and real world processes associated with the algorithm used are validated by HHS or a 3rd party?	This has always been a difficult topic and the IIS community does not see any simple answers ahead. In 2017 ONC sponsored the Patient Matching Algorithm Challenge (PMAC) whose was to allow vendors to compete for the highest performance metrics for their matching algorithms by testing their software against a large set of test data provided by ONC. Cash prizes were awarded in a number of categories, and the winning vendors were featured in the discussion on the webinar. One of the main purposes of the challenge was to promote the use of standard metrics to evaluate algorithm products. Some AIRA members were a little concerned that the winners by their own admission "analyzed patterns in the data." This seems to call into question the applicability of their results to the "real world" where you don't get to see the data set; you have to adjudicate them as they come in. That means that these particular test runs were "tuned" for the data set and the measurable results might not hold up for other data sets. Over the years, several public health initiatives have attempted to provide comparative measures of matching algorithm performance or quality and have had less than successful results.

Section, Page Number	Excerpt	Comment
Patient Matching RFI, Pgs. 7656-7	Question 2) Should CMS require Medicare FFS, the MA Plans, Medicaid FFS, Medicaid managed care plans, CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs to use a particular patient matching software solution with a proven success rate of a certain percentage validated by HHS or a 3rd party?	See response to question above.

Patient Matching RFI, Pgs. 7656-7	Question 4) Should CMS advance more standardized data elements across all appropriate programs for matching purposes, perhaps leveraging the USCDI proposed by ONC for HHS adoption at 45 CFR 170.213.	As described in an article published in 2017, ONC convened a Patient Matching Community of Practice in 2014-15. The article states, "Its major focus was developing a five-level data quality maturity model to try to characterize an organization's sophistication in using different common data elements to perform patient matching functions, as well as articulating value propositions for improved matching for different stakeholder types. The project released two documents, *Developing and Testing a Data Management Model and Maturity Scale Tailored to Improving Patient Matching Accuracy* and Guidelines for Pilot Testing of Data Management Maturity℠ Model for Individual Data Matching describing its work. The Data Quality Maturity Scale, included as Appendix B, highlights how systems across the healthcare community, at least as reflected in the core data elements, are at the high levels of maturity. In practice, however, the data elements needed for levels 4 and 5 are precisely the ones that are least consistently captured." AIRA encourages ONC to draw on these documents and resources whose development ONC funded. In addition, in January 2019 AIRA published its *IIS Functional Guide, Vol. 2: CDC Endorsed Data Elements*. This exhaustive document includes (in

		Appendix C) a list of data elements endorsed to fulfill the IIS functional standard of identifying, preventing and resolving duplicated and fragmented patient records using an automated process. This list is also worth consulting. With respect to USCDI, we note that ONC is requesting an exemption for USCDI from The National Technology Transfer and Advancement Act (NTTAA) requirements that standards adopted by the Federal government must be developed or adopted by voluntary consensus standards bodies. We do not support this exemption. The development of these artifacts has typically *not* involved public health representation; at minimum, someone should represent public health on the USCDI Task Force. Research in New York City by the Citywide Immunization Registry (CIR) has demonstrated that though matching is a complex activity, and it is difficult to tease apart factors affecting successful matching, the search success rate for the CIR was higher when more search fields were sent, especially the internal ID assigned to each patient in the CIR and available to EHRs that query the system should they choose to store it. Studies such as this one should be replicated to help determine the most effective fields for searching and matching.

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		External validation of key data elements used for matching can also be a big help. For example, in 2017 AIRA arranged access to SmartyStreets, a cloud-based address cleansing service, for all Immunization Information Systems (IIS) which chose to access it. By leveraging available CDC funding, for a modest amount this service is able to cover the *entire* IIS community and significantly increase the level of quality in address data which is often key for proper patient matching. AIRA maintains the license, provides documentation and coordination, and sponsors a monthly user group of interested IIS projects.