AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

June 20th, 2023

Micky Tripathi
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: Health Data, Technology, and Interoperability:
Certification Program Updates, Algorithm Transparency, and
Information Sharing Proposed Rule
Mary E. Switzer Building, 7033A
330 C Street SW
Washington, DC 20201

RE: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

(Comments to be uploaded at: https://www.federalregister.gov/documents/2023/04/18/2023-07229/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and#open-comment)

Dear Dr. Tripathi –

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing notice of proposed rule making. These comments are a compilation of the input of our member base which includes over 80 organizations representing Public Health Immunization Information Systems (IIS), IIS implementers and other technology vendors, stakeholder organizations and sponsors, and additional partners. Immunization Information Systems interface with a broad range of stakeholders, including health care providers using electronic health record systems, pharmacists, schools, child care facilities, health plans and payors, among others.

We greatly appreciate your leadership on advancing regulation focused on improving the nation's health and we urge ONC to finalize provisions in the proposed rule that intend to strengthen data exchange between healthcare providers using certified health information technology and public health agencies.

Our comments focus on the measures for immunization administrations electronically submitted to IIS. Our detailed comments in response to the regulation and the questions in

the proposal are found on the following pages. We leveraged the structure of the ONC-provided template to organize our comments. Please feel free to contact me with any questions: mbkurilo@immregistries.org.

Thank you again for your commitment to improving health care and health information technology. We greatly appreciate the opportunity to comment on these proposed rules, and we look forward to continuing to collaborate with ONC moving forward.

Sincerely,

Mary Beth Kurilo, MPH, MSW
Senior Director of Health Informatics, AIRA

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule

Section III – ONC Health IT Certification Program Updates

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing - General Comments

Preamble FR Citation: 88 FR 23746

On the whole, AIRA members support these proposed changes, with a few specific cautions and considerations for implementation. We appreciate the larger focus on Public Health throughout health IT interoperability and rulemaking, and we want to voice support for the further expansion of Public Health reporting requirements to continue to raise the bar for Health IT. The public health experience with the widespread adoption of the immunization-related reporting standard included in prior certification standards clearly demonstrates the effectiveness of this approach. In 2023, Immunization Information Systems (IIS) support an estimated 140,000 active HL7 V2 interfaces with data exchange partners, including Electronic Health Record Systems (EHRs), Health Information Exchanges (HIEs), pharmacy systems, and many others. The majority of these exchanges are bidirectional, allowing for both submission and query of consolidated immunization records and forecasts[1]. For the first time during the COVID-19 pandemic response, a vaccine was required to be submitted to IIS as a condition of administering vaccine, expanding the capture of data for all ages, but most markedly for adults, with the proportion of adults with two or more immunizations received in adulthood growing from ~62% in 2020 to ~89% in 2021. As a result, IIS were able to provide near real time data about vaccine uptake at the jurisdictional level (state, county, city). In addition, through deidentified case-level reporting from IIS to CDC, we had a current picture of vaccine uptake nationwide. This demonstrates the value of IIS data, and the important role these systems play across the health IT ecosystem. These data not only support local public health authorities in ensuring their jurisdictions are well-protected from disease, but also support federal efforts to monitor and ensure the health of the country.

We have the opportunity to continue to expand the secure and seamless exchange of immunization data across public and private sectors, and the ONC proposed rules will provide critical information to move us beyond the question of "CAN certified EHRs exchange data with IIS" to answer the more important question of "DO certified EHRs exchange data with IIS". For these reasons, we strongly support the inclusion of additional standards-based reporting requirements in future versions of the Certification Program.

[1] CDC IIS Annual Report: https://www.cdc.gov/vaccines/programs/iis/iisar-survey-data.html

§ 170.213 - The United States Core Data for Interoperability Standard (USCDI) v3

Preamble FR Citation: 88 FR 23762

We support the proposed changes regarding § 170.213 - The United States Core Data for Interoperability Standard (USCDI) v3. We feel that it is critical that USCDI data set continue to expand and evolve to provide improved access to a wider variety of healthcare data. The adoption of v3 will allow Public Health to better access key data elements necessary for Public Health programs, including but not limited to those related to sexual orientation and gender identity (SOGI) and social determinants of health (SDOH). We support the continued expansion of USCDI, particularly as elements aligned with Public Health goals such as maternal and child health are added.

As we've commented on in the past, there are several Level 2 data elements we would recommend considering for additions to USCDI v3 or the next upcoming version. We strongly recommend Vaccine Administration Date and Vaccination Event Record Type be added to USCDI v3 or a future version. Both elements are required for immunization exchange and always have been. With these lacking from USCDI v3 it would be possible to list only the immunization code a patient received, but not the date the patient received the dose or if the vaccination event originated in the source system. Vaccine Administration Date enables accurate record evaluation (e.g., were doses given at the proper age and at a proper interval) while Vaccination Event Record Type enable accurate inventory decrementing by public health and aids in vaccine matching/deduplication. We also believe MRN (and other IDs) along with Mother's Maiden Name and multiple birth indicator and birth order (for minors), should be moved into USCDI v3 or next upcoming version as these are key attributes in patient matching. These elements can be leveraged to greatly improve match rates when compared to records void of these extra data elements. MRN is heavily implemented in many exchanges today and Mother's Maiden Name is heavily used in pediatric/adolescent use cases such as EHR to IIS exchange.

§ 170.207 - "Minimum Standards" Code Sets Updates

Preamble FR Citation: 88 FR 23768

We support the proposed updates to newer versions of the CVX Code Set and NDC-Vaccine Linker. It remains critical that Health IT support new vaccine products as they come to market and are approved for use. We do want to emphasize, however, that the code set versions and dates cited represent a floor in terms of being current, and that health IT developers need to ensure they are adopting the newest code set available for CVX and NDC, given the frequency with which new codes are added. We further recommend that ONC explore adding MVX codes to the list of code sets to keep current.

We also recommend alignment of codes for sexual orientation and gender identity with the

work being performed by the HL7 Gender Harmony project, as well as by AIRA[2]. It is critical that the specific value sets being developed for interoperability purposes are aligned with regulatory requirements.

§ 170.315(b)(1) - Transitions of Care Certification Criterion

Preamble FR Citation: 88 FR 23821

AIRA members strongly support the proposed changes for §170.315(a)(5) Patient Demographics and Observations Certification Criterion. These additional data elements are critical to assessing the impact of Public Health events and actions on a diverse population. To support patient matching, we would also advocate for the inclusion of mother's maiden name (for minors) and multiple birth indicator and birth order (also for minors), as these are key attributes in patient matching.

§ 170.315(d)(14) - Patient Requested Restrictions Certification Criterion

Preamble FR Citation: 88 FR 23821

AIRA would encourage discussions and exploration with public health prior to implementation of this regulation to ensure there are not conflicts with public health reporting laws and policies, particularly those related to mandatory reporting and/or opt-in/opt-out consent laws.

§ 170.315(e)(1) - View, Download, and Transmit to 3rd party

Preamble FR Citation: 88 FR 23822

See above comments on § 170.315(d)(14) - Patient Requested Restrictions Certification Criterion.

§ 170.407 Insights Condition and Maintenance of Certification

Preamble FR Citation: 88 FR 23831

We support the inclusion of Public Health centered measures and encourage the addition of further Public Health reporting measures in future iterations of Insights Conditions. We would like to share some considerations and cautions, however, and encourage direct and frequent conversations between ONC and public health programs and associations. Public health programs may also be in a good position to validate or verify some of the information reported from EHRs (with sensitivity to burden and cost, of course).

[2] AIRA Guidance on Messaging Sexual Orientation and Gender Identity (SOGI): https://repository.immregistries.org/resource/guidance-on-messaging-sexual-orientation-and-gender-identity-sogi/

"Immunization Administrations Electronically Submitted to an Immunization Information System through Certified Health IT" measure

Pertaining to the first measure: "Immunization Administrations Electronically Submitted to an Immunization Information System through Certified Health IT": With regard to the request for comment on the inclusion of ACKs with a severity level of "W" for submission measure, given the definition of Warning errors supplied in guidance from our organization (AIRA), we support the inclusion of these messages as part of the numerator, as these messages were likely processed and accepted by the IIS and represent data added. With regard to the request for comment on the inclusion of "replay" messages for the "Immunization Administrations Electronically Submitted to an Immunization Information System through Certified Health IT" measure, we support the inclusion of these messages for several reasons, including (1) identification of successful messages that originally were fatally rejected by the IIS may be technically difficult for some systems to filter out, and (2) EHR users should be recognized for successful error remediation. Similarly, ONC asks if an immunization submitted to more than one IIS should count more than once, and AIRA members feel this is fair, if in fact this measure is measuring interoperability, and the potential inflation of the patient count would be minimal, as this is likely to be a rare occurrence.

We have minor concerns over the denominator definition, specifically the wording of "(1) number of administrations reported to each IIS;". The EHR is unlikely to know of administrations reported to an IIS which are not reported via HL7 v2 messaging (that is those entered directly by a web portal or through an alternate mechanism (such as a flat file upload). One possible remedy would be to create two measures:

- Out of the total number of doses administered, how many doses were submitted electronically,
- Of those electronically submitted, how many were successful?

Similarly, there may be confusion between historical vs. administered doses. If historical doses are sent to the IIS, along with newly administered doses, the number of doses submitted to an IIS could quickly exceed the number of doses administered. It might be necessary to ensure that the count of doses sent electronically only include those doses tagged as newly administered which is certainly possible but which complicates the data collection process. This concern could be mitigated by either making sure historical doses are also included in the denominator or by excluding them entirely. An alternative wording of this section might be "(1) number of administrations valid for reporting to each IIS". This would effectively be the sum of those that were successfully exchanged via HL7 v2, those for which only fatal Acknowledgments (severity of "E") were received, those reported by some non-HL7 v2 mechanism and those not reported at all.

There are other areas where ONC should be aware there may be an overcount (for example, some providers may submit a dose, delete it, then recreate it and resubmit; this

would be counted twice for a single immunization), but these numbers should be fairly small. We do support stratification by age as not all jurisdictions have comprehensive adult reporting; however, we would recommend that adolescent data extend THROUGH age 18, rather than TO age 18, to align with the Vaccines for Children program age ranges, which can have an impact on reporting. Expectations for jurisdictions who either have limited adult reporting (e.g. only COVID reporting for adults) or who have an adult "opt-in" model should be provided, as these jurisdictions will likely have a low level of reporting due to these constraints (which, ideally, should not negatively reflect on any of the IIS, EHR vendors or submitting organizations).

"Immunization History and Forecasts" measure

Pertaining to the second immunization measure "Immunization History and Forecasts": Regarding the request for comment on the inclusion of both Z32 and Z42 messages for the "Immunization History and Forecasts" measure, we support the inclusion of both message types, as they serve similar patient care purposes, contain significantly overlapping content and have both been implemented in the real-world. To exclude one of the message types would not yield a true reflection of the use of the standard.

Within the proposed rule measure specifications, it requests context for deriving measures, but says that the submission of this information is optional. We urge ONC to consider making the submission of descriptive context required, which may help with future evolution and fine-tuning of the measures.

Regarding the first denominator definition for the "Immunization History and Forecasts" measure ("The number of query responses received successfully from an IIS during the reporting period", where a successful response from an IIS is defined as the total number of messages submitted minus acknowledgements with errors (2.5.1, severity level of E), we want to clarify that an error (with a severity level of E) could be included in either an acknowledgement (ACK) or a response (RSP) message. In addition, we want to clarify that messages of "no patient found" or "too many patients found" would be considered successful, along with actual records returned. However, we also want to acknowledge another limitation of this definition of responses successfully received, in that if there is NO response from the IIS (i.e., the EHR sends 100 messages, and NOTHING is returned from the IIS), this is still considered a successful response. This gives the benefit of the doubt to the EHR (if the IIS has downtime, or is inaccessible for some reason), but we would expect that the EHR (and by extension their provider sites) would investigate and remedy these unsuccessful interfaces in collaboration with their trading partners.

As with the previous measure, we urge ONC to consider making the submission of descriptive context required, which may help with future evolution and fine-tuning of the measures.

Regarding the second denominator definition for the "Immunization History and Forecasts" measure ("The number of encounters during the reporting period"), we recognize that there is no perfect way to identify the numerator and denominator to know if an EHR, and by extension, a provider site is querying appropriately. However, we do support the concept of immunizing provider sites querying for every patient at every visit, and appreciate ONC's efforts to ensure that certified EHR products can support this concept. We would recommend modifying the second denominator to include encounters with immunizing provider sites, rather than all encounters. The language could be modified from:
"The number of encounters (see Definitions) during the reporting period."
to:
"The number of encounters at immunizing provider sites during the reporting period."

We also recognize that, even with this change, results may demonstrate a wide variety of querying practices (bulk query vs. single query, varied triggers, etc.), and the number of queries could exceed the number of encounters, resulting in a proportion greater than 100%. That being said, it would still be a beneficial overall measure to provide visibility into how much systems are querying, moving past answering the question of "can a system query the IIS" and closer to "is a system being used to query the IIS". We also strongly recommend that these measures be considered exploratory, and as such, should not be used to penalize any EHR product or vendor. The true benefits of these measures will come in viewing trends over time, rather than point-in-time insights.

Regarding ONC's question about including non-immunizers who may potentially query the IIS in the measure, although we encourage non-immunizers to query IIS, we believe this would be a difficult population to define and reach, so for simplicity, we would recommend leaving them out of this measure as a target for outreach. However, we also recognize that, due to the aggregate level of reporting, some of their queries may be represented in overall counts.

Finally, we recommend that ONC clarify the intended definitions of "50 hospital users or 500 clinician users". As written, this phrase could be interpreted as either "50 users in hospital contexts and 500 users in non-hospital (clinic) contexts" or as "50 hospital sites" or "500 clinical sites". Please clarify ONC's intended meaning.

Request for Information on Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities

Preamble FR Citation: 88 FR 23848

AIRA members support the exploration of a certification program for pharmacies; more consistent use of standards in this area will support more seamless data exchange, which will benefit public health and immunizations directly. We would also recommend

exploration of a certification program with long term care (LTC) health record systems, as the lack of standardization across this industry hinders interoperability. A certification program, along with resources to support the development and adoption of enhancements, would greatly benefit the LTC industry, and would help to protect the very vulnerable populations they serve.

Clinical Decision Support Hooks Request for Information

Preamble FR Citation: 88 FR 23855

Although as a community we support CDS Hooks, it is important to recognize that in the immunization community, CDS Hooks doesn't support all of our public health needs. Rather we see Immunization Decision Support (DS) being the primary interface for an Immunization CDS engine, and something that could be used by a CDS Hooks application to provide CDS guidance to clinicians. Public health needs the Immunization DS guide primarily and would only use CDS Hooks for clinical applications that physicians or nurses might use.

SMART Health Links Request for Information

Preamble FR Citation: 88 FR 23857

AIRA is only peripherally involved with the SMART Health Cards Framework and SMART Health Links, but we strongly support the collaborative, community-driven approach, as well as the use of open source, transparent methodology.