June 20, 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: **RIN 0955-AA03 - Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing**

Dear Dr. Tripathi,

  Thank you for soliciting feedback on the Office of the National Coordinator for Health and Information Technology's (ONC's) "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" proposed rule. We appreciate your leadership on advancing public policies affecting 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. Specifically, we are submitting comments on the proposed eCR requirements and the "Immunization Administrations Electronically Submitted to an Immunization Information System (IIS) through Certified Health Information Technology (IT)" measure.

  The Pew Charitable Trusts (Pew) is a non-profit research and policy organization dedicated to informing the public, improving public policy, and invigorating civic life with several initiatives focused on strengthening the quality of patient care and supporting public health. Specifically, Pew's Public Health Data Improvement project conducts research, provides technical assistance, and advocates for policies, resources, and public health department practices to enable the rapid and effective use of health care data to advance Americans' well-being.

  Thank you again to ONC for the opportunity to provide input and for your continued attention to this issue. We appreciate your engagement on advancing public policies affecting the nation's health. Please contact Kyle Kinner (kkinner@pewtrusts.org) in our Government Relations practice for additional information or questions.

Sincerely,

Lilly Kan
Project Director, Public Health Data Improvement
The Pew Charitable Trusts

Comments Addressing ONC's Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule

Public health agencies across the U.S. continue to face a variety of challenges in collecting and providing timely, complete, and accurate data for both public health and clinical decision-making.[1] Federal and state, tribal, local, and territorial (STLT) public health agencies are undergoing efforts to modernize their infrastructure to further enable electronic data exchange with healthcare providers and organizations, yet some of the barriers to data exchange are driven by the existing capabilities of certified health information technology (IT).[2] ONC can further enable electronic data exchange between healthcare providers and public health agencies by improving on existing requirements and creating new requirements for certified health IT that also reflect public health agency technical capabilities, thereby reducing the complexity and burden of data reporting and improving the timeliness of transmission and quality of data. By building on previous final rules, HTI-1 offers the opportunity to strengthen certified health IT to enable the electronic sharing of timely, granular, and robust data to inform decisions and actions necessary for responding to public health threats and improving population health.

Pew applauds and supports the efforts ONC has taken through its HTI-1 proposed rule to enhance data exchange between healthcare providers and STLT public health agencies through certified health IT. The following requirements in the rule and Pew's recommended modifications will improve how certified health IT electronically exchange case reporting and immunization data with public health agencies. Moreover, Pew recommends the exploration of additional possible public health use case measures beyond those proposed for immunization, such as for electronic case reporting, syndromic surveillance, and electronic laboratory reporting, to provide greater insight into nationwide data exchange capabilities.

C. New and Revised Standards and Certification Criteria
  4. Electronic Case Reporting (eCR)

Pew applauds ONC's proposal to require Health IT Modules to support eCR using consensus-based, industry-developed HL7® Clinical Document Architecture (CDA) and Fast Healthcare Interoperability Resources (FHIR)® standards. The proposal to sunset the current criterion of functional, descriptive requirements in §170.315(f)(5) by the end of 2024 and adopt consensus-based, industry-developed electronic standards and Implementation Guides (IG) will improve interoperability and implementation consistency to further enable the transmission of timely, granular, and accurate case data between healthcare providers and public health agencies. **Pew supports ONC's proposal to require a Health IT Module to enable users to create case reports and receive, consume, and process case report responses consistent with either CDA or FHIR standards described in their respective IGs.** Specifically, Health IT Modules should enable users to:

- Consume and process electronic case reporting trigger codes and parameters and identify a reportable patient visit or encounter based on a match from the Reportable Conditions Trigger Code (RCTC) value set in §170.205(t)(4) contained in the Electronic Reporting and Surveillance Distribution (eRSD) Specification Library as specified in the HL7 FHIR eCR IG in §170.205(t)(1).
- Create case reports consistent with either the Electronic Initial Case Report (eICR) profile of the HL7 FHIR eCR IG in §170.205(t)(1) or the HL7 CDA eICR IG in §170.205(t)(2).
- Receive, consume, and process a case report response formatted to either the Reportability Response (RR) profile of the HL7 FHIR IG in §170.205(t)(1) or the HL7 CDA RR IG in §170.205(t)(3).
- Support all "mandatory" and "must support" data elements as applicable in the eICR and RR profiles of their respective HL7 FHIR or HL7 CDA IGs, depending on which approach the developer chooses.

Referencing the specific IGs is critical for improving consistent implementation of standards-based requirements, which will result in improved data quality, timeliness, and completeness. While Pew recognizes that there is interest among public health agencies to leverage FHIR for data exchange, many health agencies use systems that currently handle CDA-based messages and have not yet adopted FHIR-based messaging information systems. It would be premature to require Health IT Modules to rely on FHIR standards for eCR, as it may hinder the ability of public health agencies to receive eICRs and send Reportability Responses. Pew recommends continued collaboration between ONC and the Centers for Disease Control and Prevention (CDC) to understand the implications and benefits of FHIR-adoption among STLT public health agencies, as FHIR may enable faster and more efficient data exchange than other standards such as CDA.

Additionally, Pew recognizes ONC's decision to allow developers of certified Health IT Modules to possess the capability to send a case report electronically to any system capable of receiving a case report (not requiring Health IT Modules to specifically connect to the Association of Public Health Laboratories Informatics Messaging Services (AIMS) platform or support the Reportable Conditions Knowledge Management System (RCKMS)). However, **Pew recommends that ONC considers approaches to incentivize Health IT Modules to connect to or encompass a system that offers decision support services that healthcare providers can invoke to determine if a potential case is reportable and to which jurisdictions it is reportable.** One of the unique values of RCKMS is its decision support service capability, which reduces the burden on the healthcare provider for reporting, further enabling data exchange by enhancing timeliness, accuracy, and completeness of data exchange between healthcare providers and public health agencies.[3] To further facilitate the uptake and use of decision support services, Pew recommends that ONC considers approaches to incentivize Health IT developers to implement these services in their Health IT Modules, either via RCKMS or another system with comparable capabilities.

F. Insights Condition and Maintenance of Certification
  2. Insights Condition – Proposed Measures
Measurement Area: Public Health Information Exchange Immunization Administrations Electronically Submitted to an Immunization Information System (IIS) Through Certified Health IT Measure

Pew supports ONC's proposal to adopt public health information exchange measures that would enable the agency to measure whether and to what extent providers are using certified health IT to electronically send and receive public health data to and from public health agencies. Specifically, **Pew supports the ONC's development and implementation of the "Immunization Administrations Electronically Submitted to an IIS through Certified Health IT" Measure**. This measure will provide insight into the use of certified health IT to exchange vaccination data with IIS registries by enabling ONC to calculate the percent of immunizations administered where information was electronically submitted to an IIS, which in turn will help federal agencies, public health agencies, and health IT developers better understand the extent to which health IT is exchanging data with IIS registries. Pew proposes several recommendations for ONC's consideration around this measure:

- **Pew recommends aligning analyses and interpretation of ONC's immunization measures with the Center for Medicare and Medicaid Service's (CMS) Public Health and Clinical Data Exchange Measures:** Pew appreciates ONC's acknowledgement that the proposed measures go beyond CMS's Promoting Interoperability "active engagement" measures to explore the volume of data successfully transmitted to public health agencies and immunization queries made by healthcare providers.[4] Pew recommends that ONC and CMS continue collaborating to consider how their two domains of measures (CMS's Public Health and Clinical Data Exchange measures and ONC's two new immunizations measures) can be analyzed and interpreted in tandem to answer questions about data exchange. For example, such analyses could explore the extent to which healthcare providers

(including Eligible Hospitals, Critical Access Hospitals, and Eligible Clinicians required to report on CMS's Public Health and Clinical Data Exchange measures) are reporting being in Option 2 (validated data production) for active engagement and are successfully submitting vaccine administrations to an IIS using certified Health IT (ONC's proposed measure). Aligning data and analyses from both the healthcare providers and the certified health IT systems will paint a more robust picture of whether, and to what extent, data is being exchanged between healthcare providers, IIS registries, and thereby public health agencies.

- **Pew recommends adding a timeliness component to this measure**: The Association of Immunization Registries (AIRA) defines IIS timeliness as the "amount of time between the occurrence of the real-world event and its documentation in the IIS" and recommends the development and use of timeliness targets for exchange between certified health IT and IIS registries.[5] Timeliness of immunization data exchange is critical for providers and public health agencies alike: timely immunization data enables health agencies to assess vulnerable patients at the population level during an outbreak and is useful for clinical decision support to help avoid over-vaccination. The CDC and AIRA have both recognized "timely" immunization data quality as, "95% of vaccination recorded are recorded in the IIS within 1 day." [5,6] As electronic health record (EHR) interfaces are becoming increasingly capable of sharing data in real time, it is reasonable to expect that this transaction occurs in the CDC and AIRA's 24-hour expectation.[7]

  Moreover, in 2022, Pew convened a consensus panel of experts, including EHR vendors, health information exchange representatives, public health agency leaders, public health organizations, frontline clinical providers, informatics specialists, public health and clinical researchers, and public health law and policy leaders to develop more robust quality measures for public health data exchange.[8] The panel developed a metric that would enable the measurement of immunization data exchange between an EHR and an IIS: the panel decided that adding the timeliness component to the measure would align with the CDC's expectation of receiving administered doses within one day. As such, Pew's final measure includes the timeliness component: "Successful electronic submission for a minimum of 90% of all vaccines administered within 24 hours over total administered."

  Given the consideration around the timeliness component by such a diverse panel of experts, as well as CDC and AIRA's recommendations around timeliness, Pew recommends that ONC add timeliness to this measure's numerator and stratify the measure by the definition of "timely." ONC could consider defining "timely" as immunization administrations submitted successfully to an IIS in less than or equal to 24 hours, and "not-timely" as immunization administrations submitted successfully to an IIS in greater than 24 hours. The addition of the timeliness component to ONC's proposed measure will provider health IT developers, healthcare providers, and public health agencies with insights into how rapidly immunization data is being shared with IIS registries and how rapidly health agencies can access the data.

- **Pew recommends consideration around how the measure will account for varying state consent policies:** The vast majority of U.S. states (66%) are considered "opt-out" states, meaning that patients can opt-out of sharing their vaccination data with an IIS. Several states have "opt-in" policies, meaning that patients are required to grant consent for their data to be shared with an IIS; there has been recent legislation introduced in a few additional states to move towards the "opt-in" consent model.[9,10] Given the changing landscape of state laws around consent, Pew recommends that the denominator exclude the number of patients who have opted out of vaccination reporting and consider how the measure will handle reporting in opt-in states. By excluding opt-out patients from the denominator, the measure will more accurately capture the proportion of immunization administrations electronically submitted to an IIS successfully.

Pew proposes the following recommendations to address ONC's questions related to the measure's numerator:

- **Pew recommends that Acknowledgement (ACK) messages with a warning (severity level W) should be counted in the numerator.** The HL7 immunization messaging standard includes an ACK message that is sent back to the sending system after receiving an immunization update message. The Error field documents the severity of errors that may result from the transmission. Severity is measured by three options, "Error" (E); "Warning" (W); and "Information" (I). Each option results in a specific action: an "I" value indicates that a transaction was successful, and a "W" value indicates that the transaction was successful and there may be issues. If a "W" value is received, the sender must correct the information but is not required to resubmit it. The most severe value, "E," indicates that the transaction was not successful, and the sender needs to review, correct, and resubmit the message. As such, both "I" and "W" messages should be counted in the numerator: while the sender may need to correct information, a "W" error is considered "non-fatal" and should still be counted as a "successful" transmission.[11] Additionally, Pew recommends that ONC considers the complexities of interpreting the ACK value: for example, if both the I and W messages are included in the numerator, the possibility of inflating the numerator (with W messages) is introduced, making it challenging to interpret this metric across vendors.

- **Pew recommends that a successful submission is counted if a healthcare provider is able to successfully submit to all of the registries to which the provider submitted.** Some providers operate in multiple states, resulting in the need for immunization data to be shared with more than one IIS. While the HL7 Version 2.5.1 Immunization Messaging IG states that the IIS that receives data from the healthcare provider is primarily responsible for sending data to other IIS registries, there may be situations where the provider submits data to multiple IIS registries.[12] Including submissions where the provider operating in multiple states is submitting to more than one IIS registry will provide ONC with greater insight around the interoperability between Health IT Modules and IIS registries.

- **Pew recommends that "replays" are considered successful submissions but are not counted as separate submissions.** As ONC notes in the proposed rule, it is valuable to count replays as the purpose of the proposed measure is to identify administrations successfully submitted, and not necessarily those submitted unsuccessfully on the first try. However, Pew recommends that each replay of a single immunization administration should not be counted as a separate submission, as overcounting may result in inflating the numerator of the measure. Pew recommends that ONC should collaborate with certified health IT developers to ensure that replays are not counted separately.

Pew proposes the following recommendations to address ONC's questions related to the measure's denominator:

- **Pew supports stratifying the denominator by the two proposed age groups (adults and children/infants) and does not recommend further stratifying the adolescent/infant group by age.** While stratifying the denominator by adult and children/infant age groups may provide some insight into the progress being made in immunization data exchange, this measure aims to assess the functionality of the Health IT Modules in terms of sending data to an IIS; this functionality is not determined by a patient's age. The consensus panel of experts convened by Pew in 2022 noted that when EHR data feeds are turned on to submit data to an IIS, the ability of the system to submit data is agnostic of ages and doses.[8] As such, further stratifying by age does not add additional insight into the extent to which vaccine administrations are successfully submitted. Further stratification may add unnecessary complexity to the measure; if ONC is considering additional stratifications, Pew

recommends stratifying by variables that would enable ONC to measure the functionality of the Health IT Modules, such as the timeliness of sending data, as discussed above.

- **Pew recommends that a successful submission is counted if a healthcare provider is able to successfully submit to all of the registries to which the provider submitted.** Some providers operate in multiple states, resulting in the need for immunization data to be shared with more than one IIS. As mentioned in the numerator recommendations, providers operating in multiple states may not take action to send data to more than one IIS, as this is the functionality of the IIS that received the data. However, there may be situations where the provider submits data to multiple IIS registries. Including submissions where the provider operating in multiple states is submitting to more than one IIS registry will provide ONC with greater insight around the interoperability between Health IT Modules and IIS registries.

Additional Measures and Recommendations for Future Consideration: Pew applauds ONC's recognition of the importance of assessing the ability of certified health IT to exchange data with public health agencies. **In addition to the proposed immunization measures, Pew recommends that ONC explore the feasibility of developing and adopting other public health use case measures, such as electronic laboratory reporting, electronic case reporting, and syndromic surveillance.** Measuring whether and the extent to which providers are using their certified health IT to electronically send and receive case, laboratory, and syndromic surveillance data will provide the Department of Health and Human Services and the broader public health community with greater insight into nationwide data exchange capabilities, painting a more robust picture of preparedness to detect and respond to public health threats. If ONC is already considering the development of these measures, Pew recommends that ONC publishes an estimated timeframe for the development and implementation of these measures.

As mentioned in the proposed rule, CMS's Merit-based Incentive Payment System and the Medicare Promoting Interoperability Program will require, in 2023, that Eligible Clinicians, Hospitals, and Critical Access Hospitals report on their stage of active engagement with public health agencies to electronically exchange several types of public health and clinical data, such as case, laboratory, syndromic surveillance, and immunization data.[4] **As CMS has already implemented these reporting requirements, Pew recommends that ONC aligns future public health data exchange measures with CMS's measures to better understand whether and to what extent data is being exchanged for use cases beyond immunization reporting.** While Pew recognizes that existing analyses reveal that providers may be less likely to be actively engaged in exchanging certain types of data, such as electronic case reporting, ONC could consider developing measures and implementing them strategically (e.g., in terms of timing) to better understand the extent to which these types of data are being exchanged.[13]

A few entities have taken steps to develop and implement such measures. In addition to Pew's immunization measure, as discussed above, the 2022 convenings of experts also resulted in the development of measures for electronic laboratory, case, and syndromic surveillance reporting.[8] Moreover, measures developed through Real World Testing for health IT developers participating in ONC's Health IT Certification Program could be explored as ONC continues to develop and adopt future public health exchange measures.[14] For example, Cerner's 2022 Real World Testing results included measures and metrics for syndromic and laboratory data transmission to public health agencies.[15] **As such, ONC could consider leveraging existing measures to develop its own for other public health use cases, such as electronic case, laboratory, and syndromic surveillance reporting.**

The COVID-19 pandemic illuminated gaps and challenges in the ability of public health agencies to collect and share timely, complete, and accurate data for public health and clinical decision-making. Much work needs to be done at the federal, state, tribal, local, and territorial levels to modernize public health data exchange capabilities. The ONC's proposed rule, HTI-1, offers the opportunity to address

existing gaps, particularly around electronic case reporting and immunization data exchange, which will strengthen certified health IT to enable electronic exchange of data to inform public health decision-making.

References

1. Singletary V. Modernizing Our Nation's Public Health Information System: Toward an Integrated Approach. *Public Health and Practice.* 2021;27. https://journals.lww.com/jphmp/fulltext/2021/09000/modernizing_our_nation_s_public_health_information.13.aspx
2. U.S. Centers for Disease Control and Prevention. What's in the Data Modernization Initiative? https://www.cdc.gov/surveillance/data-modernization/basics/what-is-dmi.html Web site. Updated 2023. Accessed June 1, 2023
3. Council of State and Territorial Epidemiologists. Surveillance/Informatics: Reportable Condition Knowledge Management System. https://www.cste.org/group/RCKMS. Accessed May 25, 2023
4. U.S. Centers for Medicare and Medicaid Services. 2023 Program Requirements. https://www.cms.gov/regulations-guidance/promoting-interoperability/2023-program-requirements Web site. Updated 2023. Accessed May 26, 2023
5. American Immunization Registry Association. IIS Data Quality Practices. 2019
6. U.S. Centers for Disease Control and Prevention. Immunization Information Systems Annual Report (IISAR). *U.S. Centers for Disease Control and Prevention.* 2021
7. Shen A. How ready was the US vaccination infrastructure and network of immunization information systems for COVID-19 vaccination campaigns: Recommendations to strengthen the routine vaccination program and prepare for the next pandemic. *Human Vaccines and Immunotherapeutics.* 2022;18. https://pubmed.ncbi.nlm.nih.gov/35796624/
8. The Pew Charitable Trusts. Pew Urges Federal Government to Prioritize Better Sharing of Health Data. June 28, 2021. Accessed May 26, 2023. https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2021/06/28/pew-urges-federal-government-to-prioritize-better-sharing-of-health-data
9. Coyle R. Immunization Information Systems: NCSL State Public Health Symposium. *American Immunization Registry Association.* 2022
10. Kolman S. Lawmakers Turn to Data Systems to Guide Vaccine Decision-Making. *National Conference of State Legislatures* March 28, 2023. Accessed May 25, 2023.
11. American Immunization Registry Association. Guidance for HL7 ACK Messages to Support Interoperability. 2015
12. U.S. Centers for Disease Control and Prevention and the American Immunization Registry Association. HL7 Version 2.5.1 Implementation Guide for Immunization Messaging. 2014
13. Richwine C. Electronic Public Health Reporting among Non-Federal Acute Care Hospitals During the COVID-19 Pandemic, 2021. 2022
14. Office of the National Coordinator of Health Information Technology. Real World Testing. https://www.healthit.gov/topic/certification-ehrs/real-world-testing Web site. Accessed May 23, 2023
15. Cerner. Cerner Certified Health IT 2022 Real World Testing Results. 2023