Pew

October 4th, 2024

Micky Tripathi, PhD, MPP
Assistant Secretary for Technology Policy
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services (HHS)
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street SW, Washington, DC 20201

Attention: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule, *RIN 0955-AA06*

Dear Dr. Tripathi:

Thank you for soliciting feedback on the proposed regulations issued by the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP). We appreciate your leadership on advancing public policies to advance public health interoperability and improve the nation's health. We support ASTP in finalizing provisions in the proposed rule that will strengthen data exchange between healthcare providers using certified health information technology and public health agencies. Specifically, we are submitting comments on updated standards for the United States Core Data for Interoperability, the revised and new certification criteria for health IT modules supporting public health exchange, and insights condition and maintenance certification requirements.

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 American's health and well-being.

COMMENTS ON UNITED STATES CORE DATA FOR INTEROPERABILITY

To support the goal of promoting equity, reducing disparities, and supporting public health interoperability, ASTP updated the USCDI standard from version 1 (v1) to v3, beginning January 1, 2026, in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule.[1] The new data elements in USCDI v3 provide more accurate and complete data on patient characteristics to help public health agencies identify inequities and plan targeted interventions.

Pew applauds ASTP's efforts to further advance health equity through its proposal to update the USCDI standard once again. If finalized, USCDI v4, which adds new data elements under Health Status Assessments (e.g., Alcohol Use, Substance Use), Laboratory, Vital Signs, and other data classes, would be the baseline standard beginning January 1, 2028.[2] However, USCDI v5 incorporates additional Patient Demographics/Information data elements, including Name to Use, Pronouns, and Interpreter Needed, that better support the stated goals of advancing health equity. **Pew recommends that ASTP update the standard to USCDI v5, which would provide more complete patient-level information for contact tracing, case investigation, patient outreach, and public health activities.** There is precedent of skipping versions of USCI to better help data users address health disparities. We recognize that USCDI v5 may need to be proposed in future notice of proposed rulemaking before it can be adopted.

COMMENTS ON REVISED CERTIFICATION CRITERIA FOR HEALTH IT MODULES SUPPORTING PUBLIC HEALTH DATA EXCHANGE

Pew is broadly supportive of ASTP's proposal to revise the public health certification criteria, including updates to standards and code sets, and the addition of new functional requirements. These proposals build on existing requirements and further enable electronic data exchange between healthcare providers and public health agencies. Pew provides additional comments on the following specific criteria:

§ 170.315(f)(1) – Immunization registries – Bidirectional Exchange

Pew supports ASTP's proposal to update the standard at § 170.315(f)(1) to HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, Published October 2018. The 2018 Implementation Guide, which is a compilation of the Release 1.5 version and the Addendum from 2015, would present little burden due to its widespread adoption. Although the HL7 Public Health Workgroup is working on updates to the implementation guide, the timeline for development is longer than indicated in the proposed rule and will likely not be published until late 2025/early 2026. In addition, Pew supports ASTP's proposal to update the code sets to reference more recent versions.

Pew seeks clarification from ASTP on the proposed new requirement to receive and respond to incoming patient-level immunization-specific query or request from external systems. There is no apparent use case for certified electronic health records (EHR) technology to respond to an incoming query or request the way that immunization information systems (IIS) respond.

§ 170.315(f)(3) – Reportable laboratory results – Transmission to public health agencies – and Laboratory orders – Receive and validate

Pew supports ASTP's proposals to reference updated code sets. Logical Observation Identifiers Names and Codes (LOINC®) and Systemized Nomenclature of Medicine – Clinical Terms (SNOMED CT®) are commonly used for lab test orders and results, respectively. These two data structures have been recognized for their ability to improve laboratory results' interoperability due to their consistent

meaning. USCDI v3, the baseline standard beginning in January 2026, requires LOINC for lab tests and SNOMED for lab results.[3] Further standardization via the updated code sets would improve data quality and interoperability.

Pew further supports the inclusion of the HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI), Release 1 STU Release 4 – US Realm, specifying the use of the Public Health Profile in addition to the Electronic Laboratory Reporting (ELR) Implementation Guide. Given that the certification criteria is specific to lab results being transmitted to public health agencies, Pew seeks clarification on the proposed new functional requirement to receive, validate, parse, and filter laboratory orders according to HL7 Version 2.5.2 Implementation Guide: Laboratory Orders Interface (LOI) Implementation Guide. Although the LOI implementation guide includes important patient demographic information that would support public health response, such as race, ethnicity, sex, and contact information, it is unclear if and how these data elements would be sent to public health agencies. **Pew urges ASTP to clarify whether its intent in including the LOI implementation guide is for lab orders to be sent to a public health agency ahead of the result, or if specific patient demographic information referenced in the LOI Implementation Guide should be merged with lab results data prior to being shared with public health agencies.**

§ 170.315(f)(5) – Electronic case reporting – Transmission to public health

The ultimate transition to the HL7 FHIR standard will support improved functionality and interoperability for electronic case reporting (eCR) but more time is needed for certified health information technology to have the capability to send and for public health agencies to have the capability to receive FHIR-based eCR. **Pew encourages ASTP to delay its proposed expiration of HL7 CDA R2 Implementation Guide: Public Health Case Report – the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1 – US Realm and requirement to adopt the HL7 FHIR-based eCR implementation guide standard only.** HL7 CDA messages are still commonly used by EHR vendors and public health agencies. The proposed short timeline to shift to FHIR only may present a significant burden to certified health IT vendors and public health agencies due to the need to balance preparing for FHIR adoption while also maintaining the existing infrastructure. Although some EHR vendors are using the eCR Now FHIR App, which queries the EHR via

FHIR, to send electronic case reports, many public health agencies can only accept CDA documents due to variation in capacity and infrastructure.[4] Without appropriate support or investment, a rapid transition to FHIR could hinder the utility of eCR for public health agencies.

COMMENTS ON NEW CERTIFICATION CRITERIA FOR HEALTH IT MODULES SUPPORTING PUBLIC HEALTH DATA EXCHANGE

Overall, certification of health IT for public health should aim to improve bidirectional exchange of quality, timely, and actionable data. **Pew is supportive of certification criteria for health IT for public health.** Public health agency adoption of such criteria could play an important role in furthering interoperability and would arm public health agencies with the data they need to detect, prevent, and respond to infectious diseases, environmental hazards, and other threats.

Public health agencies have historically faced challenges in collecting and providing timely, complete, and accurate data for both public health and clinical decision-making.[5] Federal and state, tribal, local, and territorial (STLT) public health agencies are undergoing substantial efforts to modernize their infrastructure to further their ability to detect diseases, characterize health conditions, and inform prevention efforts.[6] Despite these data modernization efforts, public health has not seen the same level of investment that has supported advancements in nationwide health IT infrastructure over the past couple decades.[7] There is an opportunity to use Data Modernization Initiative funding to support public health agencies in adopting new certification criteria for health IT modules supporting public health data exchange.

To learn initial thoughts and recommendations from the public health community on certification criteria for health IT for public health, Pew facilitated a dialogue in June 2024 with individuals representing the Council of State and Territorial Epidemiologists, the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, Big Cities Health Coalition, the Association of Public Health Laboratories, and the American Immunization Registry Association. Informed by that discussion**, Pew offers the following recommendations to federal agencies charged with implementing or supporting**

a program that requires or incentivizes adoption of the certification criteria for health IT for public health:

- Conduct a comprehensive analysis, inclusive of the financial impact, of public health IT certification prior to requiring certification.
- Consider prioritizing new certification criteria for (f)(21) immunizations, (f)(23) electronic lab reporting, and (f)(25) eCR. The standards referenced in these criteria are widely used by EHRs and would support bidirectional exchange of key public health data. Pew further recommends ample time be provided for public health agencies to transition to FHIR only for eCR.
- In line with recommendations made by the Advisory Committee to the Director Data Surveillance Workgroup, use a phased approach starting with guidance and requirements before advancing to certification.[8] A phased approach would help meet public health jurisdictions where they are and keep everyone moving forward.
- Provide significant and sustainable investment to support the people, process, governance, and technology associated with certification.
- Provide educational resources, training, and technical support to STLTs in meeting certification requirements.

COMMENTS ON INSIGHTS CONDITION AND MAINTENANCE CERTIFICATION REQUIREMENTS

Finalized in HTI-1, the "immunization administrations electronically submitted to immunization information systems [IIS] through certified health IT" measure allows ASTP and other federal agencies better understand the extent to which health IT is exchanging data with immunization information systems.[9] **Pew previously supported this measure[10] and is supportive of the proposed updates to the Insights Measures and technical updates to the measure specification sheets.** The HL7 immunization messaging standard includes an acknowledgement message that is sent back to the sending system after receiving an immunization message update. Severity is measured by three options: "Information" (I), "Warning" (W), and "Error" (E), with E indicating that the transaction was not successful, and the sender needs to review, correct, and resubmit the message. **Pew agrees with the proposal to add metrics to separately count acknowledgement messages with a severity level E during the reporting period overall, and by IIS and age category. Pew also agrees with the proposal to**

separately count the number of immunizations administered where an acknowledgement from an IIS is not received at all. Collecting metrics on the number of messages that were rejected, had errors, or were accepted (by IIS and age) would allow ASTP to better assess the degree to which immunization data is successfully shared by certified health IT with an IIS.

Going forward, Pew recommends ASTP consider additional measures to assess public health data exchange beyond immunization—namely, for electronic case reporting, syndromic surveillance, and electronic laboratory reporting.

Thank you again for the opportunity to provide input on these important policy proposals and for your continued attention to this issue. Please contact Kyle Kinner (kkinner@pewtrusts.org) in our Government Relations department for additional information or questions.

Sincerely,

Kathy Talkington
Director, Health Programs
The Pew Charitable Trusts

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[1] The Office of the National Coordinator for Health IT, "USCDI Version 4" PowerPoint Presentation (November 3, 2023), https://www.healthit.gov/sites/default/files/2023-11/USCDIv4_Update_CertProgram_TechForum_508.pdf; "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule)." 89:6 Fed. Reg. 1192 (January 9, 2024).
[2] The Office of the National Coordinator for Health IT, "USCDI Version 4" PowerPoint Presentation (November 3, 2023), https://www.healthit.gov/sites/default/files/2023-11/USCDIv4_Update_CertProgram_TechForum_508.pdf;
[3] The Office of the National Coordinator for Health Information Technology, "USCDI Data Classes – Laboratory" USCDI V3, https://www.healthit.gov/isa/uscdi-data-class/laboratory#uscdi-v3

[4] Association of Public Health Laboratories, "eCR Now FHIR App," https://ecr.aimsplatform.org/ecrnow-fhir-app.
[5] 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
[6] G. Birkhead et al., "Uses of Electronic Health Records for Public Health Surveillance to Advance Public Health" Annual Review of Public Health (March 2015) 36:345-59, https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122747; S. Madhavan et al., "Use of Electronic Health Records to Support a Public Health Response to the COVID-19 Pandemic in the United States: A Perspective from 15 Academic Medical Centers" Journal of the American Medical Informatics Association (February 2021) 28(2):393-401, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7665546/; J. Sharfstein, "Using Health Care Data to Track and Improve Public Health" The Journal of the American Medical Association Forum (March 2015) 313(29):2012-2013, https://jamanetwork.com/journals/jama/fullarticle/2297154.
[7] The Pew Charitable Trusts, "Closing Gaps in Data-Sharing Is Critical for Public Health: Updated federal strategy could also ease burdens on agencies, providers," June 20, 2024, https://www.pewtrusts.org/en/research-and-analysis/articles/2024/06/20/closing-gaps-in-data-sharing-is-critical-for-public-health
[8] Centers for Disease Control and Prevention Advisory Committee to the Director Data Surveillance Workgroup, *Data and Surveillance Workgroup Report*. Centers for Disease Control and Prevention: Atlanta GA; 2022, https://www.cdc.gov/about/pdf/advisory/dsw-recommendations-report.pdf.
[9] "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule)." 89:6 Fed. Reg. 1192 (January 9, 2024).
[10] The Pew Charitable Trusts, HHS-ONC-2023-0007-0048, Comments Addressing ONC's Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule (June 20, 2023), https://downloads.regulations.gov/HHS-ONC-2023-0007-0048/attachment_1.pdf.