



May 31, 2024

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1808-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-1808-P. Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Disclosures of Ownership Comment Solicitation

Dear Administrator Brooks-LaSure:

Thank you for soliciting feedback on the Centers for Medicare & Medicaid Services (CMS)'s proposed regulations to update hospital payment policies and reporting programs. We appreciate the agency's leadership on advancing public policies affecting the nation's health, and we urge CMS to consider input on strengthening the Medicare Promoting Interoperability Program, utilizing its levers to improve public health reporting, and improving the collection of race and ethnicity demographic information.

The Pew Charitable Trusts (Pew) is an independent, nonpartisan 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 best practices to enable the rapid and effective use of health care data to advance Americans' well-being.

COMMENTS ADDRESSING CMS' REQUEST FOR INFORMATION ON THE PROMOTING INTEROPERABILITY PROGRAM'S PUBLIC HEALTH AND CLINICAL DATA EXCHANGE OBJECTIVE

Responses to Questions for Goal #1: Quality, Timeliness, and Completeness of Public Health Reporting

Pew applauds CMS' ongoing efforts to improve data exchange between eligible hospitals or critical access hospitals (CAHs) and public health agencies through the Medicare Promoting Interoperability Program. Health care organizations provide essential data that public health agencies need to detect, prevent, and respond to infectious diseases, environmental hazards, and other threats. Requirements incorporated in earlier years of the program have led to notable increases in the percentage of hospitals sending data to public health agencies. For example, when electronic lab reporting was required in Stage 2 of the Meaningful Use Program, 92% of hospitals reported sending lab results electronically to public health agencies—compared to the 55% that reported doing so in the prior program stage when electronic lab reporting was not yet a required measure.¹ Immunization registry reporting was also a required measure in Stage 2 of Meaningful Use, and reporting on this measure increased by more than 40% from 2011 to 2014.² Although there have been notable increases in the share of health care providers reporting data to public health agencies, major gaps remain in the quality, timeliness, and completeness of this data.

CMS plays a vital role in supporting public health data exchange. Unfortunately, the current approach of active engagement reporting does not allow CMS to assess the level of performance that eligible hospitals and CAHs have achieved in sending this data to public health agencies. **Pew encourages CMS to shift from attestation-based measures to ones that move hospitals and CAHs towards actively demonstrating the quality, timeliness, and completeness of the data they are reporting to public health agencies.** Performance measures are essential to ensuring that hospitals and CAHs are sending high-quality, real-time information

that public health agencies can use to prevent illness and promote wellness in the jurisdictions they serve.

Pew worked directly with an external research organization from 2021-2022 to identify potential performance-based public health measures. The researchers conducted a literature review to characterize existing public health reporting processes and interviewed 34 subject matter experts in late 2021 to determine potential metrics, approaches to quality measures, and barriers to collecting timely, complete, and high-quality data. Next, the research team conducted tests within electronic health record (EHR) systems to better understand the feasibility of data extraction from EHRs for public health use cases. Finally, in March 2022, researchers convened expert panels to generate proposed measures and obtain input and agreement on them; experts included EHR vendors, health information exchange representatives, public health agency leaders, public health organizations, front-line clinical providers, informatics specialists, public health and clinical researchers, and public health law and policy leaders.

Based on our research, Pew proposes that CMS phase in the following measures for numerator/denominator reporting in the Medicare Promoting Interoperability Program:

- **Immunization registry reporting:** Successful electronic submission for a minimum of 90% of all vaccines administered within 24 hours out of total administered.
- **Electronic laboratory reporting:** A minimum of 80% of mandatory laboratory reportable cases, out of all eligible results, use two standards: Logical Observation Identifiers, Names, and Codes (LOINC) for the ordered test and Systemized Nomenclature of Medicine – Clinical Terms (SNOMED) for the result.

Using a phased approach, CMS may require numerator/denominator reporting on the measure but delay specific performance requirements in the first year. This would allow the agency to gather information on the baseline level of performance across the hospital sector, while also providing valuable data to inform and further calibrate the appropriate performance metric in the final implementation phase. This approach could be used for both the proposed immunization registry reporting and electronic lab reporting measures, and allows

CMS to make adjustments if needed to accommodate smaller or more rural facilities who may require a longer phase-in period.

For the proposed immunization measure, the expert panel recommended successful electronic submission occur within 24 hours to align with CDC's Immunization Information Systems Data Quality Blueprint, which defines timely immunization data as being recorded within one day.³ The Association of Immunization Registries (AIRA) recommends the development and use of timeliness targets for exchange between certified health information technology (IT) and immunization information system (IIS) registries to support various data needs, including during an outbreak when timely data can help public health agencies assess the vulnerability of the populations they serve.⁴ As EHR interfaces are becoming increasingly capable of sharing data in real time, it is reasonable to expect that this transaction occurs within 24 hours.

The proposed electronic laboratory reporting measure sets a threshold of 80% for the proportion of mandatory laboratory reports that use LOINC and SNOMED codes. These two data structures have been recognized for their ability to improve laboratory results' interoperability due to their consistent meanings. Further, the Office of the National Coordinator for Health Information Technology (ONC) has adopted the United States Core Data for Interoperability (USCDI) Version 3 (v3), which requires LOINC for lab tests and SNOMED for lab results, as the new baseline standard beginning in January 2026.⁵ In addition, the CMS Promoting Interoperability Program already specifies the use of LOINC and SNOMED for lab reports in regulation.⁶

In Spring 2024, Pew sought feedback on its proposed measures from the National Association of Community Health Centers (NACHC), the leading national advocacy organization in support of community health centers and the expansion of health care access for the medically underserved and uninsured and the American Immunization Registry Association (AIRA), a membership organization that promotes the development and implementation of immunization information systems as a tool for preventing and controlling vaccine-preventable diseases. NACHC is supportive of Pew's proposed measures for immunization registry and electronic laboratory reporting. Pew specifically sought feedback from AIRA on the proposed immunization measure; AIRA is also fully supportive of this measure and

agrees that it is reasonable and realistic to meet. Pew strongly recommends that CMS adopt the proposed measures in context of the additional provisions discussed below.

Pew recommends that CMS prioritize the immunization registry reporting measure for numerator/denominator reporting. CMS plays an important role in promoting timelier and more complete immunization data that would improve public health agencies' analytic capabilities to better target vaccine resources and support public health efforts. Requiring numerator/denominator reporting for the immunization measure would align CMS with ONC's final HTI-1 rule that introduced an "Insights Condition" measure that will allow ONC to calculate the percent of immunization administrations that are electronically submitted to an IIS through certified health information technology (IT) by requiring certified health IT developers to submit these metrics.⁷ While ONC can measure immunization registry reporting, CMS should incentivize health care organizations to meet an attainable but robust reporting threshold in the interest of public health. Although ONC's Insights Condition for immunization reporting does not yet include a timeliness component (e.g., within 24 hours), ONC stated that it may consider adding such a metric in the future.⁸

Pew further recommends that CMS align its timeline for implementing the proposed immunization registry reporting measure with ONC's timeline for phasing in the Insights Condition immunization measure requirement for certified EHR technology. ONC will require certified health IT developers to submit the number of immunizations administered overall and the number of immunizations administered that are successfully electronically submitted to IISs overall in Year 1, which starts in calendar year 2026.⁹ Responses are due in July 2027, and annually thereafter.¹⁰ Eligible hospitals and CAHs should only be required to report this data after certified EHR technology developers can demonstrably collect and provide this data. Aligning timelines with ONC could reduce the burden of reporting this revised immunization measure for eligible hospitals and CAHs.

Pew is supportive of a bonus, attestation-based measure on the use of Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs) to support electronic case reporting (eCR) to public health agencies. FHIR

promises to be a critical tool for improving data sharing between hospitals and public health agencies. Groups like the Helios FHIR Accelerator for Public Health, which aims to ensure public health data needs are considered as the FHIR standard evolves, are currently exploring ways to improve interoperability while also aligning with public health priorities.¹¹ Recognizing progress in the use of FHIR for public health, ONC now requires that certified EHR technology support eCR using either Health Level 7 (HL7) Clinical Data Architecture (CDA) or FHIR standards.¹² Some EHR vendors are already using the eCR Now FHIR App, which automates the electronic reporting of cases of COVID-19 and can be configured to support full eCR, to send electronic case reports in a FHIR format, and many others are in the process of adopting its use.¹³ Although progress has been made in the use of FHIR for public health, many public health agencies can only accept HL7 CDA documents. Therefore, it would be premature for CMS to measure performance without more time or resources made available to public health agencies to ensure that their IT systems can receive electronic case reports according to the FHIR standard. Pew recommends that an attestation-based measure assessing the use of FHIR for eCR be introduced as a bonus measure, rather than a required one, to better align with ONC's regulatory flexibility that allows certified EHR technology to create an electronic case report based on either the CDA or FHIR standard.

The electronic reporting of notifiable health conditions can improve the flow of timely, standardized, and complete information to public health agencies about what diseases and conditions are prevalent in their communities. However, much more progress is needed to increase adoption of eCR. According to Pew research conducted between May and August 2021, there were no states that use eCR for all reportable conditions.¹⁴ And just 33% of health care facilities and 28% of CAHs use eCR to report data.¹⁵ Recent improvements, spurred by advances in eCR for COVID-19, have been made in public health's ability to receive data for other conditions.¹⁶ The CDC aims to increase the number of CAHs in production with eCR and the number of jurisdictions receiving electronic case reports for at least 75% of their jurisdictional reportable conditions.¹⁷ CMS can play a role in incentivizing eCR and supporting federal efforts to increase adoption but because notifiable conditions vary by jurisdiction, it would be challenging for CMS to set a single national benchmark for eCR at this time. Pew recommends that CMS explore one of two options to remedy this challenge: **1) CMS could incentivize an eCR measure that accounts for various jurisdictional requirements for mandatory reportable**

conditions; or 2) CMS—in close collaboration with the CDC, state and local public health partners, and other stakeholders—could determine which conditions are most critical to electronically report to public health agencies, then incentivize reporting of those conditions. Determination of those conditions could set a national floor and CMS could incentivize the electronic reporting of those conditions for public health surveillance, potentially improving eCR for more conditions. Such a measure should include exclusions or phase-in's to account for public health agency readiness to ingest data for these conditions.

As CMS considers additional levers besides the Medicare Promoting Interoperability Program for improving the completeness of reporting to public health agencies, Pew has identified two opportunities that warrant CMS' consideration for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category. First, **if CMS phases in Pew's proposed performance-based immunization registry reporting measure in the Promoting Interoperability Program, an analogous change to the immunization measure in the MIPS Promoting Interoperability performance category should be made.** Many vaccinations are administered in outpatient care settings and CMS updating the immunization registry reporting measure in MIPS would incentivize the electronic submission of those vaccinations to an IIS. Second, **Pew urges CMS to require the submission of the syndromic surveillance reporting measure in MIPS.** Outpatient physicians working outside of emergency departments, such as those who practice at urgent care facilities, generate meaningful syndromic surveillance data that would substantially benefit public health agencies' ongoing disease surveillance. As more and more patients are visiting urgent care clinics instead of emergency departments, public health agencies may be missing critical data to detect and respond quickly to emerging threats. Officials in many states find that the Medicare Promoting Interoperability effectively incentivizes hospitals to report syndromic surveillance data.¹⁸ Requiring the syndromic surveillance reporting measure under MIPS could similarly incentivize eligible providers to report this data. Moreover, a requirement to report syndromic data in MIPS would better align with the reporting requirement in the Medicare Promoting Interoperability Program and would enable public health agencies to expand the data sources they receive. Given the significance to current and future public health efforts, CMS should require syndromic surveillance reporting in future payment policies under MIPS.

Responses to Questions for Goal #2: Flexibility and Adaptability of the Public Health Reporting Enterprise

In 2018 and 2019, the top two public health reporting challenges experienced by hospitals were interface-related issues (e.g., costs, complexity) and lack of capacity (e.g., technical, staffing) to electronically exchange information, with small, rural, independent hospitals and CAHs being more likely to report interface-related issues.¹⁹ In 2022, roughly three-quarters of hospitals experienced at least one challenge to public health reporting, with the two most-commonly reported challenges related to the onboarding process and cost.²⁰ Moreover, a 2023 U.S. Government Accountability Office report found that small and rural hospitals lag behind their larger and non-rural counterparts in their reported use of electronic methods of health information exchange.²¹ To potentially remedy these challenges, **Pew recommends that CMS, in close collaboration with ONC, explore offering a payment adjustment for small, independent hospitals and CAHs to update their health IT systems to meet new data needs.** It is critical that smaller, lower-resourced health organizations are not left behind in data modernization efforts. CMS may consider defining “small, independent hospitals” as those with 100 beds or fewer that are not part of a chain organization, as defined elsewhere in the proposed rule.²² ONC could provide ongoing guidance to CMS on the requirements for certified EHR technology to ensure that provider systems continue to meet minimum data standards.

Responses to Questions for Goal #3: Increasing Bi-Directional Exchange with Public Health Agencies

Pew supports the introduction of a measure to allow providers to receive credit for the Health Information Exchange (HIE) objective by exchanging public health data through participation in the Trusted Exchange Framework and Common Agreement (TEFCA). Through its Public Health Infrastructure Grant, CDC has funded the Association of State and Territorial Health Officials, the Network of Public Health Institutes, and the Public Health Accreditation Board to select three Implementation Centers to support public health agencies in accelerating public health agency data modernization activities, including conducting TEFCA-based data exchange. This effort aligns with CDC’s Public Health Data Strategy, in which

CDC aims to launch at least two public health use cases for TEFCA in 2024, and two additional ones in 2025.²³ While CDC provides technical assistance and other support to public health agencies to conduct TEFCA-based data exchange, CMS can incentivize eligible hospitals and CAHs to exchange public health data via TEFCA. Stakeholders have acknowledged the potential benefits of TEFCA for public health in fostering interjurisdictional data exchange, reducing costs associated with connecting to multiple, different networks, and improving availability of quality data.²⁴ Incentivizing the exchange of public health data through participation in TEFCA will help CDC increase provider reporting and strengthen bi-directional exchange with public health agencies.

Responses to Questions for Goal #4: Eliminating Reporting Burden for Healthcare Providers

As CMS continues to consider performance-based public health measures, Pew encourages the agency to work closely with ONC to align any revised measures with future iterations of ONC's Insights Condition measures to reduce reporting burden for healthcare providers. ONC has expressed an interest in introducing new Insights Condition measures, such as for electronic laboratory reporting, eCR, and syndromic surveillance.²⁵ As Health IT vendors build the capability to capture this data into their EHR and other reporting systems, CMS can incentivize performance in its payment policies by setting defined targets. Coordination across the two agencies would promote further consistency across programs and potentially reduce the burden on healthcare providers.

COMMENTS ON COLLECTING DATA BY RACE AND ETHNICITY

Pew commends CMS' commitment to promoting health equity and supports the agency's proposed requirements for reporting race and ethnicity demographic information. Such data are necessary to detect and respond to disparities and advance health equity. Yet despite its importance, this data is often missing from health records and other data systems. For instance, in March 2021, COVID-19 surveillance systems were missing race and ethnicity data for 42% of nationwide cases.²⁶ And data on race and ethnicity was only present for 51.9% of COVID-19 vaccine recipients based on data from early COVID-19 vaccine reporting.²⁷

Pew recommends that CMS align its demographic data reporting requirements with federal initiatives aimed at collecting more comprehensive race and ethnicity data. In March 2024, the Office of Management and Budget revised Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) to require the collection of more detailed race and ethnicity data.²⁸ The revisions are intended to result in more accurate, useful race and ethnicity data across the federal government. ONC’s Health IT Certification Program currently references an older version of SPD 15, but it is reasonable to expect ONC’s adoption of the revised version within the five-year implementation period.²⁹ In addition, ONC requires certified EHR technology to enable an end user to record, change, and access patient demographic data, including race and ethnicity.³⁰ Collection of race and ethnicity data would be in line with federal requirements and EHR technical capabilities.

Thank you again to CMS for the opportunity to provide input 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,

A handwritten signature in cursive script that reads "Lilly Kan". The signature is written in black ink and has a fluid, connected style.

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

¹ Office of the National Coordinator for Health Information Technology, “Hospital Selection of Public Health Measures in Medicare EHR Incentive Program,” Health IT Quick-Stat #16, November 2016, <https://www.healthit.gov/data/quickstats/hospital-selection-public-health-measures-medicare-ehr-incentive-program>.

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- ² Centers for Medicare & Medicaid Services, “Stage 2 Overview Tipsheet,” news release, August 2012, https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/stage2overview_tipsheet.pdf; Office of the National Coordinator for Health Information Technology, “Electronic Reporting to Immunization Information Services (IIS) among Medicare Eligible Professionals, 2011-2014,” Health IT Quick-Stat #48, July 2015, <https://www.healthit.gov/data/quickstats/electronic-reporting-immunization-information-services-iis-among-medicare-eligible>.
- ³ Centers for Disease Control and Prevention. *Immunization Information Systems Data Quality Blueprint*. Centers for Disease Control and Prevention: Atlanta GA; 2020, <https://www.cdc.gov/vaccines/programs/iis/downloads/Data-Quality-Blueprint-508.pdf>.
- ⁴ American Immunization Registry Association. IIS Data Quality Practices. 2018, https://repository.immregistries.org/files/resources/5c002cbde216d/aira_dq_guide_data_at_rest_-_final.pdf.
- ⁵ “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule).” 89:6 Fed. Reg. 1192 (January 9, 2024); 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>.
- ⁶ 45 CFR pt 170.315(f)(3)(ii) Transmission to public health agencies – reportable laboratory tests and value results.
- ⁷ “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule).” 89:6 Fed. Reg. 1192 (January 9, 2024).
- ⁸ Ibid.
- ⁹ Ibid.
- ¹⁰ Office of the National Coordinator for Health Information Technology, “HTI-1 Insights Condition Fact Sheet,” December 2023, https://www.healthit.gov/sites/default/files/page/2023-12/HTI-1_Insights_factsheet_508.pdf
- ¹¹ J. Procius, “Helios FHIR Accelerator for Public Health Home” (February 2024), <https://confluence.hl7.org/display/PH>.
- ¹² “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule).” 89:6 Fed. Reg. 1192 (January 9, 2024).
- ¹³ Association of Public Health Laboratories, “eCR Now FHIR App,” <https://ecr.aimsplatform.org/ecr-now-fhir-app>; A.D. Schmit, Disease Surveillance and Data Modernization Lead, personal communication with The Pew Charitable Trusts, May 15, 2024.
- ¹⁴ The Pew Charitable Trusts, unpublished data.
- ¹⁵ C.A. Wong, D. Houry, and M.K. Cohen, “Integrating Public Health and Health Care – Protecting Health as a Team Sport,” *N Engl J Med* 2024, <https://doi.org/10.1056/nejmp2403274>; Centers for Disease Control and Prevention, “PHDS Milestones for 2024 and 2025.” Centers for Disease Control and Prevention: Washington DC; 2024, <https://www.cdc.gov/ophdst/public-health-data-strategy/phds-milestones.html>.
- ¹⁶ Council of State and Territorial Epidemiologists, DMI Stories from the Field: Electronic Case Reporting, https://stories.cste.org/?page_id=449.

¹⁷ The Centers for Disease Control and Prevention, “PHDS Milestones for 2024 and 2025.” Centers for Disease Control and Prevention: Washington DC; 2024, <https://www.cdc.gov/ophdst/public-health-data-strategy/phds-milestones.html>.

¹⁸ The Pew Charitable Trusts, unpublished data.

¹⁹ C. Richwine, C. Marshall, C. Johnson, & V. Patel, “Challenges to Public Health Reporting Experienced by Non-Federal Acute Care Hospitals,” *ONC Data Brief* no. 56 (September 2021). Office of the National Coordinator for Health Information technology: Washington DC. Accessed at: <https://www.healthit.gov/sites/default/files/page/2021-09/Challenges-to-PH-Reporting.pdf>

²⁰ C. Richwine, “Progress and Ongoing Challenges to Electronic Public Health Reporting Among Non-Federal Acute Care Hospitals,” *ONC Data Brief* no. 66 (June 2023). Office of the National Coordinator for Health Information Technology: Washington DC. Accessed at: https://www.healthit.gov/sites/default/files/2023-06/AHA-Public-Health-Data-Brief_508.pdf.

²¹ U.S. Government Accountability Office, “Electronic Health Information Exchange: Use Has Increased, but Is Lower for Small and Rural Providers,” GAO Publication No. 23-105540 (April 2023), Washington, D.C. Retrieved from: <https://www.gao.gov/assets/gao-23-105540.pdf>.

²² CMS-1808-P; FY 2025 IPPS Proposed Rule, <https://public-inspection.federalregister.gov/2024-07567.pdf>.

²³ Centers for Disease Control and Prevention, “Public Health Data Strategy Milestones for 2024 and 2025,” (April 11, 2024), <https://www.cdc.gov/ophdst/public-health-data-strategy/phds-milestones.html>.

²⁴ Association of Public Health Laboratories, “Comments on the Draft Trusted Exchange Framework and Common Agreement”, February 2018, <https://www.aphl.org/programs/informatics/Documents/Comments%20on%20the%20Drafted%20Trusted%20Exchange%20Framework%20and%20Common%20Agreement.pdf>; American Immunization Registry Association, “Public Comment of Draft Trusted Exchange Framework and US Core Data for Interoperability”, February 2018, https://repository.immregistries.org/files/resources/5a85e9510ecfe/aira_letter_and_comments_-_trusted_exchange_framework_final_new_logo-1.pdf.

²⁵ “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (Final Rule).” 89:6 Fed. Reg. 1192 (January 9, 2024).

²⁶ K.R. Spangler, et al., “Missing Race and Ethnicity Data among COVID-19 Cases in Massachusetts,” *J Racial Ethn Health Disparities* 2023; 10(4): 2071-2080, <https://doi.org/10.1007%2Fs40615-022-01387-3>.

²⁷ E.M. Painter et al., “Demographic Characteristics of Persons Vaccinated During the First Month of the COVID-19 Vaccination Program,” *Morbidity and Mortality Weekly Report* 70, no. 5 (February 5, 2021): 174-77, <https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7005e1-H.pdf>.

²⁸ “Revisions to OMB’s Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (Final Rule).” 89 Fed. Reg. 22182 (March 29, 2024).

²⁹ 45 CFR pt 170.207(f) Race and Ethnicity.

³⁰ 45 CFR 170.315(a)(5) Patient demographics and observations.