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Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1771-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-1771-P. Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Changes to Hospital and Critical Access Hospital Conditions of Participation: Proposed Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective—Antimicrobial Use and Resistance (AUR) Surveillance Measure and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals

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 your leadership on advancing public policies affecting the nation's health, and we urge CMS to finalize provisions in the proposed rule that are key to combating the growing and urgent threat of antibiotic-resistant bacteria and to strengthening the Medicare Promoting Interoperability program by addressing aspects of electronic health record (EHR) use that aid public health efforts and expand health information exchanges (HIEs).

The Pew Charitable Trusts is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care. Specifically, Pew's Antibiotic Resistance project advocates for policies that establish and sustain stewardship programs to ensure that antibiotics are prescribed in health care settings only when necessary; and 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 CMS for the opportunity to provide input and for your continued dedication to this issue. Please contact Kyle Kinner (kkinner@pewtrusts.org) in our Government Relations practice for additional information or questions.

Sincerely,

Kathy Talkington
Director, Health Programs
The Pew Charitable Trusts

Comments Related to Changes to Hospital and Critical Access Hospital Conditions of Participation: Proposed Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective—Antimicrobial Use and Resistance (AUR) Surveillance Measure.

Antibiotic resistance is one of the greatest public health threats of our time. Drug-resistant infections sicken at least 2.8 million people and kill at least 35,000 people in the United States each year. In 2019, there were more deaths worldwide caused by antibiotic-resistant bacteria than those caused by either HIV or malaria. Additionally, antibiotic resistance accounts for direct health care costs of at least \$20 billion and imposes broader economic and health systems costs as high as \$1.2 trillion. If we do not act now, antibiotic resistant infections will be the leading cause of death by 2050 and could cost the world \$100 trillion.

Effective antibiotics are essential to modern medicine as we know it. Clinicians rely heavily on antibiotics to treat serious and life-threatening infections that complicate procedures such as cancer chemotherapy, dialysis, Cesarean sections, care of wounds and burns, joint replacements, transplants, and other surgeries. And, as we have witnessed throughout the COVID-19 pandemic, antibiotics are also critical during public health emergencies—used to treat secondary bacterial infections, often in medically complex or ventilated patients, and to combat related spikes in healthcare-associated infections.

Notably, the Centers for Disease Control and Prevention (CDC) reported a significant increase in health care-associated infections during the pandemic, many of which were caused by antibiotic-resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA). And a CDC investigation into a December 2020 superbug outbreak at a COVID-19 hospital unit in New Jersey highlighted “that multidrug-resistant organisms can spread rapidly in hospitals experiencing surges in COVID-19 cases and cause serious infections.”

Ultimately, any public health emergency is likely to strain hospitals’ and health care systems’ capacity to deliver high-quality care and increase the risk of drug-resistant infections. Without effective antibiotics, these superbugs will only exacerbate the deadly consequences of future pandemics. Policymakers must prioritize U.S. preparedness to combat antibiotic resistance by strengthening our commitment to evidence-based stewardship programming and robust data collection, reporting and resistance monitoring throughout the continuum of care that patients experience.

We applaud CMS for including provisions in its FY 2023 IPPS Proposed Rule that **require hospitals and critical access hospitals to report antibiotic use and resistance (AUR) data into the CDC’s National Healthcare Safety Network (NHSN)**, the nation’s most widely used healthcare-associated infection tracking system, as a required measure to satisfy the Public Health and Clinical Data Exchange Objectiveⁱ. We also agree that the proposed implementation timeline for this measure within the EHR reporting period of CY 2023 is fully consistent with the clinical and public health value of timely AUR surveillance reporting and appropriate for most hospitals. However, a subset of smaller and resource-limited facilities may need a limited period of additional “phase-in” time, not to exceed two years, to fully meet the new reporting requirements.

Antibiotic use and resistance reporting to a centralized registry provides vital data for health care facilities, policy makers, and local, state, and federal agencies to assess emerging and endemic resistance trends over time, enabling clinicians and public health officials to identify resistant pathogens and improve clinical decision-making. Comprehensively capturing and reporting this data to NHSN is also a key component of antibiotic stewardship, which is not only essential to preserving the effectiveness of existing drugs and slow the spread of superbugs but is also proven to enhance patient outcomes and lower health care costs. We agree with CMS’ assessment in the proposed rule that widespread reporting of antibiotic use and resistance data is essential to identifying and tracking emerging threats and to evaluate the impact of interventions to address antibiotic resistance. CMS’s proposed mandatory requirement for NHSN reporting, as described in the FY 2023 IPPS Proposed Rule, will be a critical step in advancing U.S. efforts to combat antibiotic-resistant bacteria and to

prepare for future superbug outbreaks and pandemics.

This new policy should drive increased investment in NHSN from Congress and CDC to provide financial support and technical assistance to help facilities report data to NHSN, with a focus on small, rural, and critical access facilities that may need more assistance to fully comply. Lack of resources must not be allowed to become a barrier to effective implementation of this essential reporting requirement.

Comments Related to the Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals

Pew commends the efforts CMS has taken to enhance data exchange between these entities through the Medicare Promoting Interoperability Program and supports CMS in building on its previous actions to strengthen incentives that further drive public health reporting. By continuing to address aspects of EHR use that aid public health efforts and leverage HIEs, CMS can compel providers to electronically share timely, granular, and robust data that inform decisions and actions essential for responding to public health threats, reducing health inequities, and improving population health.

The proposed rule updates payment policies for hospitals and seeks comment on the Medicare Promoting Interoperability Program—which encourages health care facilities to use EHRs in meaningful ways. As proposed, the following modifications and requirements in the rule would continue to significantly improve how EHRs help inform public health agencies’ activities and automatically report data to authorities:

- **Public Health and Clinical Data Exchange Objective**
 - Pew supports the consolidation of options from three phases to two, in which the level of active engagement for eligible hospitals and critical access hospitals (CAHs) must occur in one of the following two phases:
 1. Pre-production and validation (i.e., the eligible hospital or CAH has completed registration to submit data *and* is in the process of testing and validating electronic data submission); or
 2. Validated data production (i.e., the eligible hospital or CAH has completed testing and validation of electronic data submission and is electronically submitting production data – data generated through clinical processes involving patient care – to the public health agency or clinical data registry);
 - Pew supports the requirement for eligible hospitals and CAHs to submit their level of active engagement; and
 - Pew supports an increase in points allocated to the Public Health and Clinical Data Exchange (CDE) Objective.

- **HIE Objective**
 - Pew supports the addition of an alternative, attestation-based measure for enabling exchange under the Trusted Exchange Framework and Common Agreement (TEFCA).

Pew further recommends continued and expanded efforts to (1) mandate or otherwise support adherence to guidelines and standards in partnership with the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Disease Control and Prevention (CDC); and (2) specify that any reporting measures must also consider completeness of data, as part of improving quality electronic data reporting to public health agencies.

Proposed Changes to the Medicare Promoting Interoperability Program

Requiring Active Engagement and Increasing Points for Public Health and CDE Measure within Public Health and Clinical Data Exchange Objective

Pew applauds CMS' recognition of important efforts that need to continue in moving providers and health care organizations toward electronically submitting data to public health agencies. Public health authorities obtain critical data from health care organizations through case reporting, lab reporting, syndromic surveillance, and sharing of vaccination information. In earlier years of the program, requiring electronic reporting for several of the public health objective measures has clearly yielded major improvements. 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.² Immunization reporting was also a required measure in Stage 2 of Meaningful Use.³ As providers advanced from Stage 1 to Stage 2 over the course of several program years, reporting to the immunization registry measure increased by almost half.⁴ With the program now requiring reporting for four use cases, electronic reporting to public health agencies can similarly grow across data types. Given the significance to current and future public health efforts, it is important for CMS to continue to support the transition to this process in the final rule.

While public health authorities rely on data from health care providers, major gaps remain in the timeliness and completeness of this data. These gaps have hindered the comprehensive actions necessary for a swift, timely response throughout the COVID-19 pandemic. For example, from early COVID-19 vaccine reporting, data on race and ethnicity is present in only 51.9% of cases.⁵ Manual case reporting, or the non-electronic transmission of results through modalities such as faxes, also results in delays and widespread under-reporting. The CDC estimates that, in some circumstances, as few as 1 in 10 reportable cases are sent to public health agencies after a medical encounter.⁶ Without this information, officials cannot adequately track the spread of a public health threat or understand its impact on different communities.

Not all providers are involved in active electronic data exchange despite having technology with the capability to send information using automated, standard mechanisms. Pew agrees with CMS that knowing the level of active engagement, by requiring eligible hospitals and CAHs to submit this detail, will help to identify gaps in progress and inform efforts to address them. Pew supports the concept of limiting the duration of primary levels of active engagement per reporting period to incentivize the increased utilization of electronic exchange by hospitals; however, Pew recognizes that smaller, resource-limited facilities may need additional phase-in time and technical assistance to fully meet this requirement. Pew previously recommended increasing the weighting of the Public Health and Clinical Data Exchange Objective from 10 to 20 points and supports the steps CMS is taking to reflect the value of this objective.⁷

The proposed updates to the Promoting Interoperability program will provide additional incentives for providers to use existing electronic data exchange capabilities and improve public health data for COVID-19 and future threats. In future efforts, CMS can go further to ensure that public health agencies receive timely and complete data. Pew recommends the future implementation of more robust public health measures with numerators and denominators that enable opportunities to quantify quality data exchange. Pew previously noted it was undertaking a process to identify more robust, quality data measures. Pew has since submitted conceptual candidate measures for CMS consideration and looks forward future engagements with CMS and other stakeholders to refine these measures through further specification and testing.⁷

Enabling Exchange under TEFCA via a Measure within the HIE Objective

Pew believes CMS' proposed new measure within the HIE Objective is an important step in increasing provider engagement in progress toward nationwide bidirectional health information exchange. Bidirectional exchange means that data is shared between EHRs and HIEs or other systems, and that providers can both view and incorporate information into EHRs. This ensures that critical clinical data becomes part of the medical record, regardless of where a patient received care. Without these connections, health information will remain segmented, meaning providers may continue to struggle to access complete data—which can lead to medication errors and

expensive duplicative testing, among other risks.⁸

The principles for nationwide health information exchange laid out in TEFCA reflect a network-of-networks structure and allow connections at different levels through a single on-ramp, for a wide range of entities.⁹ While much work remains to implement and fulfill the vision of TEFCA, stakeholders have acknowledged its potential benefits for public health in fostering interjurisdictional data exchange, reducing costs associated with connecting to multiple, different networks, and improving availability of quality data.^{10, 11}

Incentivizing connectivity with HIEs and engagement in health information networks may help increase provider reporting; as more health care organizations exchange data with HIEs, patients will have more comprehensive records and providers can access more complete information. As the current COVID-19 pandemic demonstrates, integrated and comprehensive medical records are essential for ensuring the delivery of appropriate care and preventative measures.

Pew agrees that including an additional measure for an eligible hospital or CAH to earn credit for the HIE Objective by connecting to a qualified health information network (either directly or indirectly) would incentivize participation in TEFCA. This will continue to support bidirectional information exchange in a flexible manner that reflects broader federal progress toward increasing opportunities to enable exchange under TEFCA. Pew appreciates CMS' efforts to encourage and increase participation in bidirectional information exchange, and the agency should include this measure in the final rule as written.

Additional Considerations for Addressing Health Equity

The collection of complete data can be a key component to address health equity. Using outdated mechanisms in public health data reporting both increases the risk of human error and can allow for the omission of important demographic information. For example, 85% of all COVID-19 lab results that state health agencies received in the early stages of the pandemic did not include the individual's race or ethnicity, and half were sent without their addresses.¹² Increasing electronic data-sharing with public health agencies can help ensure that health officials have better data to improve decision-making, and address disparities. CMS can encourage hospitals and providers to use these reporting tools by requiring quality data submission for reimbursement. CMS can also coordinate with the ONC to mandate that EHR vendors build in functions that let providers collect and report electronic, standardized, and demographically detailed data.

Recommendation: CMS should specify that reporting must be complete, and mandate adherence to specific standards in partnership with ONC. Completeness of race and ethnicity data is critical to support health equity, both during a crisis like the COVID-19 pandemic and for other reportable conditions that pose longer-term challenges. Additionally, complete information on reporters, providers, performing facilities, and specimen type is integral to timely public health investigation and follow-up activities. The development of more robust measures could help assess compliance more easily. To improve the completeness of submitted data, CMS should also work with ONC to identify new standards, where appropriate, and require adherence to existing ones. Where they exist—often as Health Level 7 implementation guides—adherence to such standards should be required to meet the Promoting Interoperability measures.

The COVID-19 pandemic highlighted gaps in data exchange that limited the effectiveness of public health action and failed to make the most of existing technologies. Through the proposed updates to the Promoting Interoperability program, CMS will help to increase adoption of electronic reporting to public health agencies. Additionally, these connections should follow national standards and send all of the data elements that public health officials need—such as phone number, address, race, and ethnicity—to conduct contact tracing, investigate cases, assess disparities, and track the efficacy of treatments or vaccine distribution.

Promoting Interoperability could provide the incentive needed to spur national adoption of public health data exchange and ensure that providers and public health agencies are exchanging vital data needed to safeguard and improve public health.

¹ Proposed Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective: Antimicrobial Use and Resistance (AUR) Surveillance Measure, at Fed. Reg., Vol. 87, No. 90, p. 28586 (May 10, 2022).

² Office of the National Coordinator for Health Information Technology, “Hospital Selection of Public Health Measures in Medicare EHR Incentive Program,” November 2016, <https://dashboard.healthit.gov/quickstats/pages/FIG-MU-Hospitals-Public-Health-Measure-Attestations.php>.

³ 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.

⁴ The Office of the National Coordinator for Health Information Technology, “Electronic Reporting to Immunization Information Services (IIS) among Medicare Eligible Professionals, 2011-2014,” accessed February 12, 2021, April 2015, <https://dashboard.healthit.gov/quickstats/pages/medicare-eps-immunization-registry-reporting-trend.php>.

⁵ 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>.

⁶ L.A. Conn et al., “eCR Now: A Webinar Describing Efforts to Scale Case Reporting Nationwide” (presentation, AMIA 2020 COVID-19 Webinar Series, April 28, 2020), <https://amia.org/news-publications/amia-covid-19-resource-center/amia-covid-19-webinar-series/ecr-now-webinar>.

⁷ The Pew Charitable Trusts, “Pew Urges Federal Government to Prioritize Better Sharing of Health Data” comment letter, June 2021, <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>.

⁸ R.S. Huckman and M. Uppaluru, “The Untapped Potential of Health Care APIs,” *Harvard Business Review*, December 2015, <https://hbr.org/2015/12/the-untapped-potential-of-health-care-apis>.

⁹ The Office of the National Coordinator for Health Information Technology, “Common Agreement for Nationwide Health Information Interoperability Version 1”, January 2022, https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.

¹⁰ 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>.

¹¹ 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.

¹² R. Pifer, “Public Health Agencies, Commercial Labs Warn Patchy IT Infrastructure Hindering COVID-19 Response,” *Health Care Dive*, <https://www.healthcaredive.com/news/public-health-commercial-labs-CDC-health-it-coronavirus-covid19-test/576189>.