

F. CoP Requirements for Hospitals and CAHs to Report Acute Respiratory Illnesses

1. Background

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the state Medicaid agency, as appropriate. Hospitals (all hospitals to which the requirements of 42 CFR part 482 apply, including short-term acute care hospitals, LTC hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals) and CAHs seeking to be Medicare and Medicaid providers of services under 42 CFR part 485, subpart F, must be certified as meeting Federal participation requirements. Our conditions of participation (CoPs), conditions for coverage (CfCs), and requirements set out the patient health and safety protections established by the Secretary for various types of providers and suppliers. The specific statutory authority for hospital CoPs is set forth in section 1861(e) of the Act; section 1820(e) of the Act provides similar authority for CAHs. The hospital provision at section 1861(e)(9) of the Act authorizes the Secretary to issue any regulations he or she deems necessary to protect the health and safety of patients receiving services in those facilities; the CAH provision at section 1820(e)(3) of the Act authorizes the Secretary to issue such other criteria as he or she may require. The CoPs are codified at 42 CFR part 482 for hospitals, and at 42 CFR part 485, subpart F, for CAHs.

Our CoPs at § 482.42 for hospitals and § 485.640 for CAHs require that hospitals and CAHs, respectively, have active facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases and for the optimization of antibiotic use through stewardship. Additionally, the programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the required hospital and CAH programs must

also be addressed in coordination with facility-wide quality assessment and performance improvement (QAPI) programs.

Infection prevention and control is a primary goal and responsibility of hospitals and CAHs in their normal day-to-day operations, and these programs have been at the center of initiatives taking place in hospitals and CAHs since the beginning of the Public Health Emergency (PHE) for COVID–19. Our regulations for hospitals and CAHs at §§ 482.42(a)(3) and 485.640(a)(3), respectively, require infection prevention and control program policies to address any infection control issues identified by public health authorities.

On March 4, 2020, we issued guidance stating that hospitals should inform infection prevention and control services, local and state public health authorities, and other health care facility staff as appropriate about the presence of a person under investigation for COVID-19 (QSO-20-13-Hospitals). CMS followed this guidance with an interim final rule with comment period (IFC), “Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,” published on September 2, 2020 (85 FR 54820), that required hospitals and CAHs to report important data critical to support the fight against COVID-19. The IFC provisions specifically required that hospitals and CAHs report specified information about COVID-19 in a format and frequency specified by the Secretary. Examples of data elements that could be required to be reported included things such as the number of staffed beds in a hospital and the number of those that are occupied, information about its supplies, and a count of patients currently hospitalized who have laboratory-confirmed COVID-19. These elements proved essential for developing and directing implementation of infection prevention and control guidance, as well as resource allocations and technical assistance during the PHE.

On August 10, 2022, we finalized revisions to the COVID–19 and Seasonal Influenza reporting standards for hospitals and CAHs (at §§ 482.42(e) and (f); and 485.640(d) and (e),

respectively) in the FY 2023 IPPS final rule “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates” (87 FR 48780, 49409), to require that, beginning at the conclusion of the COVID–19 PHE declaration and continuing until April 30, 2024, hospitals and CAHs must electronically report information about COVID–19 and seasonal influenza virus, influenza-like illness, and severe acute respiratory infection in a standardized format specified by the Secretary. In establishing these requirements, we stressed that such reporting continued to be necessary for CMS to monitor whether individual hospitals and CAHs were appropriately tracking, planning for, responding to, and mitigating the spread and impact of COVID-19 and influenza on patients, the staff who care for them, and the general public (87 FR 49377). We also noted that the approach finalized in that rule would provide a path towards ending the overall reporting of COVID–19-related data between the end of the current PHE and April 2024, when those requirements would sunset (87 FR 49379).

2. Hospital Respiratory Illness Data Are and Will Continue to Be Critical for Patient Health and Safety

The COVID-19 pandemic highlighted the importance of taking a broad view of patient safety—one that recognizes patient safety is determined not just by what is happening at the bedside, but also what is happening in the broader hospital, and in hospitals across the region, state, and country. At the same time, it also demonstrated the patient benefits of strong integration between public health and health care systems, particularly when data are available to direct collaborative actions that protect patient and public health and safety. Data from health care providers remain the key driver to identify and respond to public health threats, yet health care and public health data systems have long persisted on separate, often poorly compatible tracks.

Hospital and CAH-reported data on COVID-19, influenza, and RSV infections among patients, as well as hospital bed capacity and occupancy rates, continue to play a critical role in

infection prevention and control efforts at every level of the health system. The value of these data extend beyond the COVID-19 PHE. For example, source control remains an important intervention during periods of higher respiratory virus transmission.⁸⁰⁸ Data on hospital admissions reported under the current CoPs continue to inform national, state, and county recommendations for community and health care mitigation measures.⁸⁰⁹ Notably, the CDC recommends that health care facilities consider levels of respiratory virus transmission in the whole community when making decisions about source control. Comprehensive and consistent surveillance across hospitals creates a shared resource that all health care facilities in a community can use to inform infection control policies. Hospitals and CAH requirement to report this data ends in April 2024. Not maintaining this reporting would result in an absence of vital information on local, regional, and national transmission and impact of respiratory illness, with significant implications for both patient care and public health mitigation.

The data produced by hospital respiratory virus reporting requirements under the PHE informed coordination of hospital operations and were especially important to anticipate and prepare for surge conditions. Collaborative, data driven approaches can help to manage patient transfers and alleviate strained hospitals, ultimately aiding to improve patient care. Medical operations coordination centers (MOCCs) and similar structures showed promise as effective tools for facilitating medical surge response.⁸¹⁰ MOCCs are often rapidly stood up as needed and

⁸⁰⁸ https://www.cdc.gov/infectioncontrol/guidelines/core-practices/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fhicpac%2Frecommendations%2Fcore-practices.html

⁸⁰⁹ Infection Control: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) | CDC; 2023.12.14 - IDPH Recommends Healthcare Facilities Adopt Mitigation Measures as Respiratory Viruses Increase (illinois.gov) 2024-doh-masking-advisory.pdf (ny.gov); Health Alert Network (HAN) - 00503 | Urgent Need to Increase Immunization Coverage for Influenza, COVID-19, and RSV and Use of Authorized/Approved Therapeutics in the Setting of Increased Respiratory Disease Activity During the 2023 – 2024 Winter Season (cdc.gov)

⁸¹⁰ Hick, J. L., Hanfling, D., & Wynia, M. (2022). Hospital Planning for Contingency and Crisis Conditions: Crisis Standards of Care Lessons from COVID-19. *Joint Commission journal on quality and patient safety*, 48(6-7), 354–361. <https://doi.org/10.1016/j.jcjq.2022.02.003>

US Department of Health and Human Services . 2nd ed. Medical Operations Coordination Cells Toolkit; Nov 2021. Office of the Assistant Secretary for Preparedness and Response; Technical Resources, Assistance Center, and Information Exchange. <https://files.asprtracie.hhs.gov/documents/fema-mocc-toolkit.pdf> Accessed Jan 30, 2024.

Valin JP, et. al. Physician executives guide a successful COVID-19 response in Colorado. *NEJM Catalyst*. Epub

reliant on shared visibility across multiple, often competitive, hospitals. Standardized data collections enable MOCCs and other partners to support patient placements and transfers and identify patient load balancing needs.⁸¹¹ This helps the health care community to prepare for and effectively respond to respiratory illness surges in ways that maintain the safety and availability of critical care services. MOCCs or similar structures were implemented in multiple jurisdictions to help place patients and mitigate strain.⁸¹² Even without formal MOCCs, jurisdictions, health care coalitions, and health systems have used hospital capacity data to coordinate patient placement and reduce ED boarding and overcrowding.⁸¹³ These efforts are especially critical as surge conditions can impact quality of care and patient outcomes - many COVID-19 deaths were potentially attributable to surge-strained hospitals.⁸¹⁴ The data reported under the COP were important to inform MOCC operations and identify and mitigate strain on health care systems.

Insight into hospital and CAH capacity helps ensure capabilities are available to meet patient needs with quality care through enhanced planning, technical assistance, resource allocation, and coordination.⁸¹⁵ While health care entities often work independently within their own systems, health care partners are ultimately part of an ecosystem caring for patients in their community. This interdependency is especially highlighted during times of strain – whether it is due to temporary conditions such as diversion, permanent changes with facility closures, or

2021 Oct 15. Accessed Jan 30, 2024. <https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0402>.

Villaruel L. Collaboration on the Arizona surge line: how COVID-19 became the impetus for private, public, and federal hospitals to function as one system. *NEJM Catalyst. Epub.* 2021 Jan

⁸¹¹ <https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/WA-HospitalSurge-March2020.aspx> (March 2020)

⁸¹² <https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/CO-Combined-Hospital-Transfer-Cntr.aspx>

⁸¹³ e.g., Alaska Hospital Capacity Dashboard (arcgis.com); <https://files.asprtracie.hhs.gov/documents/aspr-tracie-hcc-engagement-in-covid-19-assessment.pdf>

⁸¹⁴ Kadri SS, Sun J, Lawandi A, et al. Association between caseload surge and COVID-19 survival in 558 U.S. hospitals, March to August 2020. *Ann Intern Med.* Jul 06 2021.174(9):1240–1251.

Auld SC, Caridi-Scheible M, Blum JM, et al. ICU and ventilator mortality among critically ill adults with coronavirus disease 2019. *Crit Care Med.* 09 2020;48(9):e799–e804

Keene AB, Admon AJ, Brenner SK, Gupta S, Lazarous D, Leaf DE, Gershengorn HB; STOP-COVID Investigators. Association of Surge Conditions with Mortality Among Critically Ill Patients with COVID-19. *J Intensive Care Med.* 2022 Apr;37(4):500-509. doi: 10.1177/088550666211067509. Epub 2021 Dec 23. PMID: 34939474; PMCID: PMC8926920.

⁸¹⁵ <https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/Kentucky-Collaborates-Community.aspx>

PHEs. Regardless of facility status, the need for patient care remains - resulting in increased strain on surrounding hospitals. Health care coalitions (HCCs) are one example of local health care partners working together to increase local and regional health care resilience during respiratory illness surges and more.⁸¹⁶ HCCs plan and respond together, sharing real-time information and providing technical assistance to support their partners.⁸¹⁷ At the state level, in addition to patient placements and load balancing operations, hospital associations and state health departments have used hospital data to monitor for potential trends and to inform their response. Hospital capacity data helped to inform and monitor triggers for patient load balancing, allocations of scarce resources, and requests for additional resources or mutual aid.⁸¹⁸ Hospitals and health care systems can also use the information for planning purposes, identifying how their facility may be impacted and to help prepare accordingly.⁸¹⁹ Information sharing across the health care ecosystem helps the health care community to prepare for, and effectively respond to, respiratory illness surges in ways that maintain the safety and availability of critical care services.

Data from hospitals play a central role in guiding actions to reduce the prevalence of respiratory infections in the community.⁸²⁰ In recognition of this point, the Biden-Harris Administration’s National Biodefense Strategy includes a goal to, “maintain and enhance an enduring domestic all-hazards hospital data collection capability, including data reporting and management systems, governance processes, and user guidance, to enable comprehensive data reporting for biosurveillance, situational awareness, and emergency response operations at the federal and STLT levels.”⁸²¹

⁸¹⁶ <https://aspr.hhs.gov/HealthCareReadiness/HealthCareReadinessNearYou/Documents/HCC-FactSheet-April2021-508.pdf>

⁸¹⁷ <https://aspr.hhs.gov/HealthCareReadiness/HealthCareReadinessNearYou/Documents/HCC-FactSheet-April2021-508.pdf>

⁸¹⁸ Mitchell SH, Rigler J, Baum K. Regional Transfer Coordination and Hospital Load Balancing During COVID-19 Surges. *JAMA Health Forum*. 2022;3(2):e215048. doi:10.1001/jamahealthforum.2021.5048

<https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/HCC-Regional-Approach-Illinois.aspx>

⁸¹⁹ <https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/Maryland-HCC-covid19.aspx>

⁸²⁰ COVID-19 Surveillance After Expiration of the Public Health Emergency Declaration — United States, May 11, 2023 | MMWR (cdc.gov)

⁸²¹ [National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf](#) (whitehouse.gov)

The prevalence of respiratory infections in the community affects patient safety within hospitals in at least two ways: First, community prevalence is a key risk factor for within-facility pathogen transmission. Higher infection prevalence in the community unavoidably translates to higher prevalence among staff, patients, and visitors entering a facility. The more times a pathogen is introduced into a facility, the more times it has a chance to spread onward within that facility. Within-facility infection control measures can substantially mitigate this risk, but no single action confers absolute protection—rather, layered mitigation measures, particularly when those include community level actions, are most effective. Second, the community prevalence of respiratory infections is a key driver of health care worker absenteeism, which can lead to staff shortages that adversely affect patient safety.

Data on hospitalizations feature prominently on CDC’s website and are directly tied to specific disease-prevention guidance (for example, whether mask-wearing is recommended in public indoor spaces). Additionally, analyses that measure the trajectory of waves of COVID-19 and seasonal influenza and analyses that generate forecasts have relied on nationally comprehensive data on hospital admissions.⁸²² Similarly, scenario models that have been used to generate seasonal projections for COVID-19 and that have informed vaccination policy are based on hospital admissions data.⁸²³ The incidence of COVID-19 and influenza hospital admissions inform urgent messages from CDC on actions health care providers can take to protect their patients from respiratory viruses.⁸²⁴ No other data source available to CDC has the same level of timeliness, geographic resolution and coverage, and interpretability as nationally comprehensive hospitalization surveillance.

Respiratory illness reporting proved invaluable during the COVID-19 PHE, and these data have significant and ongoing value for protecting patient health and safety. While the

⁸²² CFA and NCIRD Modeling and Forecasting of Respiratory Diseases (cdc.gov)

⁸²³ Public health impact of the U.S. Scenario Modeling Hub - ScienceDirect

⁸²⁴ Health Alert Network (HAN) - 00503 | Urgent Need to Increase Immunization Coverage for Influenza, COVID-19, and RSV and Use of Authorized/Approved Therapeutics in the Setting of Increased Respiratory Disease Activity During the 2023 – 2024 Winter Season (cdc.gov)

COVID-19 PHE has ended, SARS-CoV-2 continues to circulate throughout the globe. Although COVID-19 activity and hospitalization rates have been lower, than those of 2020 through early 2022, there was no epidemiologic bright line associated with the end of the PHE. For example, in January 2024, COVID-19 hospital admissions were only modestly lower than they were at the July 2022 or December 2022 peaks.⁸²⁵ At the same time, other respiratory viruses have seen a resurgence, and the moderate COVID-19 burden coinciding with resurgent influenza and RSV has led to an overall hospitalization burden larger than observed during severe influenza and RSV seasons prior to the COVID-19 pandemic, placing patient health and safety at risk.⁸²⁶

The result of this “new normal” will be more burdensome respiratory virus seasons for the foreseeable future, which promises to place continued strain on the nation’s hospitals.⁸²⁷ In response to this changed landscape, public health agencies such as CDC have shifted prevention and control strategies from a focus on specific viruses to an approach that addresses the threats presented by the broader respiratory virus season, including overall impacts on hospital capacity and patient health and safety.⁸²⁸

The elevated risks of respiratory viruses in the post-PHE era present ongoing threats, both direct and indirect, to patient health and safety. As discussed elsewhere in this proposed rule, the COVID-19 PHE strained the health care system substantially, introducing new safety risks and negatively impacting patient safety in the normal delivery of care. Data from the pandemic showed that the incidence of health care associated infections would increase when COVID-19 hospitalizations were high,⁸²⁹ creating a feedback loop between increased stress on hospitals,

⁸²⁵ https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_select_00

⁸²⁶ [Respiratory Disease Season Outlook \(cdc.gov\)](#)

⁸²⁷ [Respiratory Disease Season Outlook \(cdc.gov\)](#)

⁸²⁸ See <https://www.cdc.gov/respiratory-viruses/index.html> and data summaries of respiratory virus burden at <https://www.cdc.gov/respiratory-viruses/data-research/dashboard/snapshot.html>.

<https://www.cdc.gov/respiratory-viruses/whats-new/track-hospital-capacity.html>

⁸²⁹ Continued increases in the incidence of healthcare-associated infection (HAI) during the second year of the coronavirus disease 2019 (COVID-19) pandemic | Infection Control & Hospital Epidemiology | Cambridge Core; <https://www.nejm.org/doi/full/10.1056/NEJMp2118285>; [The impact of coronavirus disease 2019 \(COVID-19\) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network - PubMed \(nih.gov\)](#); [Impact of COVID-19 pandemic on central-line-associated bloodstream infections during the early months of 2020, National Healthcare Safety Network - PubMed \(nih.gov\)](#)

increased illness in the community, and negative effects on patient health and safety.

Degradation in other measures of patient safety, including pressure ulcers and falls, further demonstrate how the strains associated with surge response adversely affect routine safety practices.⁸³⁰ Elevated respiratory virus activity also impacts patient access to hospital care and services and the resiliency of the health care system overall. During the most severe waves of respiratory illness, hospitals see delays in elective procedures, bed capacity issues that require diversion, and other disruptions to routine patient care.⁸³¹

3. Proposal to Continue Respiratory Illness Reporting in a Modified Form

In light of continued utility of respiratory illness data, we propose to revise the hospital and CAH infection prevention and control and antibiotic stewardship programs CoPs to extend a modified form of the current COVID-19 and influenza reporting requirements that will include data for RSV and reduce the frequency of reporting for hospitals and CAHs. These proposed requirements would take effect on October 1, 2024. While hospitals and CAHs are encouraged to voluntarily continue reporting these data in the interim, we recognize that there would be a 5-month gap between the sunset date for current reporting requirements (April 30, 2024) and the proposed implementation date for these new requirements. We welcome public comment on strategies to mitigate challenges and support an informed transition.

Specifically, we propose to replace the COVID-19 and Seasonal Influenza reporting standards for hospitals and CAHs at § 482.42(e) and (f) and § 485.640(d) and (e), respectively, with a new standard addressing respiratory illnesses to require that, beginning on October 1, 2024, hospitals and CAHs electronically report information about COVID-19, influenza, and RSV in a standardized format and frequency specified by the Secretary. To the extent determined by the Secretary, [we propose that](#) the data elements for which reporting would be

⁸³⁰ <https://www.nejm.org/doi/full/10.1056/NEJMp2118285>

⁸³¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9526134/>; Infect Control Hosp Epidemiol. 2022 Oct;43(10):1473-1476.doi: 10.1017/ice.2021.280. Epub 2021 Jun 24.; [Changes in the number of intensive care unit beds in US hospitals during the early months of the coronavirus disease 2019 \(COVID-19\) pandemic - PubMed \(nih.gov\)](#)

required at this time include--

- Confirmed infections of respiratory illnesses, including COVID-19, influenza, and RSV, among hospitalized patients;
- Hospital bed census and capacity (both overall and by hospital setting and population group [adult or pediatric]); and
- Limited patient demographic information, including age.

We considered the data elements that proved most actionable and informative over the course of the COVID-19 PHE with evidence of protecting health and safety, as well as more recent lessons that have emerged during the 2023-2024 respiratory virus response.⁸³² We also considered ways to balance the burden of reporting on hospitals and CAHs with the need to maintain a level of situational awareness that will benefit hospitals and the patients and communities they serve. Therefore, outside a declared national PHE for an acute respiratory illness (as discussed further below), we propose that hospitals and CAHs would have to report these data on a weekly basis (either in the form of weekly totals or snapshots of key indicators) through a CDC-owned or supported system.

Sustained data collection and reporting outside of emergencies would help ensure that hospitals and CAHs maintain a functional reporting capacity that can be mobilized quickly when a new threat emerges to inform and direct response efforts (for example, resource allocations or patient load balancing within and across facilities) that protect patients and their communities. It will also provide the baseline data necessary to forecast, detect, quantify and, ultimately, direct responses to signals of strain. For example, to estimate the extent to which a novel SARS-CoV-2 variant threatens hospital capacity, analysts need data on a population's epidemiologic history (for example, the presence and magnitude of prior waves of SARS-CoV-2) and they need data to infer the relationship between respiratory virus admissions and strain on hospital capacity.

Unlike the previous and sunseting hospital and CAH reporting CoPs, the reporting

⁸³² <https://emergency.cdc.gov/han/2023/han00503.asp>, <https://emergency.cdc.gov/han/2023/han00498.asp>

requirements proposed in this rule are not tied to a specific PHE declaration. PHE declarations are valuable tools to marshal nimble and fast emergency responses. However, there are many respiratory disease threats to hospital operations and patient safety that would not necessarily be subject to a PHE declaration nor have significant potential to become a PHE. In those instances, routine data about influenza hospitalizations and admissions are critical to inform allocation of resources to hospitals and planning to prevent disruptions to patient care.

These proposals are scaled back and tailored from the current post-COVID-19 PHE requirements, continuing the collection of the minimal necessary data to maintain a level of situational awareness that would benefit patients and hospitals across the country while reducing reporting burden on hospitals and CAHs.

We welcome public comments on our proposals, and on ways that reporting burden can be minimized while still providing adequate data. We also welcome feedback on any challenges of collecting and reporting these data; ways that CMS could reduce reporting burden for facilities; and alternative reporting mechanisms or quality reporting programs through which CMS could instead effectively and sustainably incentivize reporting. Finally, we welcome comments on the value of these data in protecting the health and safety of individuals receiving treatment and working in hospitals and CAHs.

4. Soliciting Input on Collecting Data by Race and Ethnicity

The COVID-19 pandemic devastated communities across the United States, and socially vulnerable populations have been disproportionately affected. From the beginning, reports indicated that people of color and people from economically disadvantaged communities were at an increased risk of becoming sick from COVID-19, being hospitalized due to COVID-19, and dying from COVID-19, compared to members of predominantly white and/or affluent communities.⁸³³ At the same time, the data necessary to detect and respond to these disparities

⁸³³ <https://oig.hhs.gov/oei/reports/OEI-05-20-00540.asp>;
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9533809/#:~:text=In%20this%20study%20coho>

were not consistently available from core data sources, including hospitalization data reported by hospitals and CAHs under §§ 482.42(e) and (f); and 485.640(d) and (e), respectively.

We are committed to protecting patients from all communities and preventing inequities caused or exacerbated by respiratory viruses like COVID-19, influenza, and RSV. Timely, complete data on racial and ethnic differences in hospitalizations are critical to meeting that commitment in policy solutions. In addition, timely, complete data on granular demographic information can assist us in assuring the health and safety of individuals receiving health care services to the greatest extent possible. For that reason, we seek comment on expanding the scope of demographic information collection to further support improvements in clinical outcomes while also protecting privacy and the safety of demographic groups.

At the same time, we recognize that efforts to improve the collection of race/ethnicity data and standards for how these data are captured are still evolving.⁸³⁴ We also recognize that in the context of aggregate data collection, requesting multiple demographic details for each data element may increase data collection and reporting burdens.

For this reason, we invite comment as to whether race/ethnicity demographic information should be explicitly included as part of requirements for ongoing reporting beginning on October 1, 2024. We are particularly interested in comments that address the ways these additional data elements could be used to better protect patient and community health and safety both during and outside of a declared PHE. We are interested in comments on how to protect patient privacy within demographic groups and best use the data to inform public health efforts without stigmatizing demographic groups.⁸³⁵ We are also interested in comments that address system

rt%2C%2062,%2C%20and%205%25%20were%20Hispanic.

⁸³⁴ <https://www.federalregister.gov/documents/2023/01/27/2023-01635/initial-proposals-for-updating-ombs-race-and-ethnicity-statistical-standards>

⁸³⁵ Landers S, Kapadia F, Tarantola D. Monkeypox, After HIV/AIDS and COVID-19: Suggestions for Collective Action and a Public Health of Consequence, November 2022. *Am J Public Health.* 2022 Nov;112(11):1564-1566. doi: 10.2105/AJPH.2022.307100. PMID: 36223580; PMCID: PMC9558195. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9558195/>

readiness and capacity to collect and report these data. Finally, we request comments as to whether the additional demographic factors including socioeconomic or disability status that may be associated with disparities in outcome, should be required for mandatory ongoing reporting starting on October 1, 2024. After considering the public comments on this issue, we may decide to finalize a policy of collecting demographic information on race/ethnicity and/or additional factors

5. Proposal to Collect Additional Elements During a PHE

Routinely collected data from hospitals also power forecasts that inform decision making during an emergency response.⁸³⁶ In the face of future illness emergencies, we anticipate stakeholders—including health care systems—will continue to need data on how respiratory illnesses are affecting and burdening the health care system. Better understanding anticipated impacts empower hospitals and CAHs, health systems, and jurisdictions to take steps that protect patient safety and health care system capacity in the face of surges in respiratory virus cases, including low-probability, high-impact events such as pandemics that pose catastrophic risks to patient safety and the health care system. These include facility-initiated actions, such as delaying elective procedures or activating contracts for additional surge staffing support, as well as jurisdiction or federal-level actions to mobilize supplies, staffing, or other forms of support. Collaborations during the COVID-19 pandemic demonstrated the value of bringing together analysts, public health officials, and health care practitioners and leaders to use advanced analytics to guide emergency response, and data from hospitals were central to some of these efforts.⁸³⁷ The federal government has made significant investments to consolidate these gains and develop response-ready analytic tools that work at scale to meet the needs of the health care and public health systems.⁸³⁸

⁸³⁶ JMIR Preprints #54340: Responding to the return of influenza in the United States: applying CDC surveillance, analysis, and modeling to inform understanding of seasonal influenza

⁸³⁷ Real-time pandemic surveillance using hospital admissions and mobility data | PNAS
Coordinated Strategy for a Model-Based Decision Support Tool for Coronavirus Disease, Utah, USA - Volume 27, Number 5—May 2021 - Emerging Infectious Diseases journal - CDC

⁸³⁸ cdc-cfa-annual-report-2023.pdf

These proposed requirements would provide a foundation for response-ready hospitals, CAHs, and the broader health system. However, we also recognize that, while necessary, they may not be sufficient in the course of an actual emergency response. Accordingly, we propose that--

- During a declared federal, state, or local PHE for an infectious disease the Secretary may require hospitals to report data up to a daily frequency without notice and comment rulemaking.
- During a declared PHE for infectious disease, the Secretary may require the reporting of additional or modified data elements relevant to infectious disease PHE including but not limited to: confirmed infections of the infectious disease, facility structure and infrastructure operational status; hospital/ED diversion status; staffing and staffing shortages; supply inventory shortages (for example, equipment, blood products, gases); medical countermeasures and therapeutics; and additional, demographic factors..
- If the Secretary determines that an event is significantly likely to become a PHE for an infectious disease, the Secretary may require hospitals to report data up to a daily frequency without notice and comment rulemaking.

We invite comments on if, during a PHE, there should be any limits to the data the Secretary can require without notice and comment rulemaking, such as limits on the duration of additional reporting or the scope of the jurisdiction of reporting (that is, state or local PHEs). We also seek comments on whether and how the Secretary should still seek stakeholder feedback on additional elements during a PHE without notice and comment rulemaking and how HHS should notify hospitals of new required infectious disease data. We also invite comments on the evidence HHS should provide to demonstrate: (1) that an event is “significantly likely to become a PHE”; or (2) that the increased scope of required data will be used to protect patient and community health and safety. Finally, we invite comment on whether hospitals should be incentivized for this data if the burden of collecting and reporting reaches a certain threshold of cost or time.

6. Collaboration

To further reduce burden in the short term, we will work with the CDC to ensure hospitals can continue to use existing, established systems to report data in the interim. The CDC will continue increasing the automation capabilities of the surveillance systems like NHSN and its ability to connect with other data submission techniques, vendors, and systems. The CDC, CMS, and ASPR are also working with Office of the National Coordinator for Health Information Technology (ONC), jurisdictions, health information technology (health IT) vendors, hospitals and CAHs, and other public and private partners to establish national standards and interoperability requirements that reduce burden and promote standardization. We request comment from facilities on the existing, established data systems; what has worked well and what has been the challenges? Do facilities recommend alternative data reporting mechanisms?

We recognize that some of the proposed data elements are currently reported via multiple mechanisms, and this could place unnecessary burdens on hospitals. If finalized, CMS, CDC, and ASPR will work with hospitals, health systems, and state, territorial, local and tribal agencies (STLTs) to streamline this federal, state, and local reporting burden, utilizing the least burdensome technical exchange mechanism for reporting. CDC and ASPR, together with ONC, would also take steps to encourage state, local, jurisdictional partners to utilize the same HHS-adopted health IT standards like USCDI for data exchange, which would further reduce burden on health care systems. We will also explore where guidance can leverage data sets being developed under the USCDI+ initiative, which focuses on develop and advancing use of standardized data elements for exchange for additional use cases that build on the USCDI.⁸³⁹

CMS, CDC, and ASPR recognize the immense value of partnerships with hospitals, health systems, STLTs, associations, and other partners. Throughout the COVID-19 PHE, partners at all levels worked alongside CMS, CDC, and ASPR to provide additional context,

⁸³⁹ For more information about USCDI+ <https://www.healthit.gov/topic/interoperability/uscdi-plus>

insight, and feedback based on conditions on the ground. This context helped data collections be more effective and helped provide a fuller picture than data alone. CMS, CDC, and ASPR are grateful for the many collaborations with partners on data and beyond. CDC, ASPR, and ONC will explore opportunities to codify continued partnerships to prepare for and respond to incidents such as respiratory illnesses more effectively. We welcome public comment on ways that all public agencies involved in these types of data collections can be good partners.

7. Request for Information on Health Care Reporting to the National Syndromic Surveillance Program

CDC's National Syndromic Surveillance Program (NSSP) is a collaboration among CDC, other federal agencies, local and state health departments, and academic and private sector partners who have formed a Community of Practice. They collect, analyze, and share electronic patient encounter data received from emergency departments, urgent and ambulatory care centers, inpatient health care settings, and laboratories.

The electronic health data are integrated through a shared platform; the BioSense Platform. The public health community uses analytic tools on the platform to analyze data received as early as 24 hours after a patient's visit to a participating facility. Public health officials use these timely and actionable data to detect, characterize, monitor, and respond to events of public health concern.

The primary dataset used for analysis is Emergency Department patient visit data obtained through data leveraging HL7v2 ADT-based messaging among CDC, local and state health departments, and the nation's acute care hospitals. By tracking symptoms and diagnoses of patients using this electronic health data source, analysts can detect unusual levels or changing patterns of illness. Every day, more than 2,000 users (analysts at all levels of government including 73 state and local health departments) conduct 4,000 searches of these data for response, decision-making, and action. In 2022-23, these data were used to provide critical insights for more than 40 responses across infectious diseases (including COVID-19, RSV,

influenza, tickborne disease, domestic polio, and Mpox), disasters (including hurricanes and typhoons, extreme heat and cold, flooding, chemical exposure, food and water contamination), injuries (including overdose, poisonings, boating injuries in collaboration with the Coast Guard, child abuse and elder abuse) and for mental health, mass gatherings, and other conditions. These data provide public health with a common situational awareness of health threats over time and across regional boundaries. New responses between 2022 and 2023 included the Mpox public health emergency, domestic malaria, asthma from Canadian wildfire smoke, Hurricane Ian, Typhoon Mawar, volcanic eruption in Hawaii, the train derailment in Ohio, hepatitis of unknown cause in children, encephalitis and meningitis in young children, group A Streptococcal Disease, and pertussis. Nationwide, CDC's NSSP data are presented on many local, state, and federal public websites.

CDC's NSSP data provide crucial insights that inform hospital preparedness and better prepare for emerging health events. Syndromic surveillance relies on the secondary use of EHR data that supports delivery of care, enabling an efficient and cost-effective way to identify and characterize public health threats. The provision of these data requires no ongoing action from a health care provider, with data exchange automated from the EHR.

Currently, CDC receives data from 78 percent of the non-federal emergency departments across 50 states, Washington D.C., and Guam. In most cases, the technical pathway for these data is from health care facilities' and health care systems' EHRs to their state or local public health agency, which then further shares these data with CDC. However, a number of other options exist, and CDC has worked with Health Information Exchanges, EHR vendors, and individual facilities and health systems to support the technical provisioning of ED data feeds to CDC's NSSP and to supplement the technical capacity of some state and local public health agencies. Recognizing the tremendous value that these data offer in providing a fast and broad look at the trends and patterns of illness and injury across the county, CDC is seeking to close the remaining participation gap to ensure all communities served by acute care hospitals and

CAHs are well represented in CDC's NSSP.

The current level of reporting and participation has been the result of many years of active effort by state and local public health agencies, CDC, and hospitals devoted to building a broad network of data providers and program participants. The CMS EHR Incentive Program, and subsequently the Promoting Interoperability Program, have helped to incentivize and offset some of the health care system investment that has been needed for this public health reporting activity to occur. However, some challenges remain in closing the participation gap. In some instances, data are already being shared locally between health care and public health agencies, but they are not yet provided to the national system, CDC's NSSP. In other cases, some health care facilities have not yet begun providing data despite their jurisdictional public health agency already actively participating in CDC's NSSP.

Syndromic surveillance is not a part of any condition of participation under this program, but the continued growth of national syndromic surveillance would benefit hospitals, health care, and public health. The goal of this RFI is better understand what else can be done to ensure that this effort can continue to make progress and that this critical data source is available at all levels of public health to support health care preparedness, public health readiness, and responsiveness to existing and emerging health threats. We seek input on the following:

- How can CMS further advance hospital and CAH participation in CDC's NSSP?
- Should CMS require hospitals and CAHs to report data to CDC's NSSP, whether as a condition of participation or as a modification to current requirements under the Promoting Interoperability Program?
- Should CMS explore other incentive or existing quality and reporting programs to collect this information?
- What would be the potential burden for facilities in creating these connections in state and local public health jurisdictions that have not yet established syndromic programs and /or where state and local public health are not presently exchanging data with CDC's NSSP? Are

there unique challenges in rural areas that CMS should take into consideration?

- Data reported as part of syndromic surveillance requirements could serve as an alternative source for the COVID-19, influenza, and RSV hospitalization reporting requirements proposed in this rule—and even support eventual evolution towards an all-hazards approach for monitoring inpatient hospitalizations for conditions of public health significance. Should CMS consider a future requirement or otherwise incentivize facilities to expand ADT-based reporting currently provided for emergency department visits to include data collected from inpatient settings as defined in the HHS COVID-19 reporting guidance,⁸⁴⁰ or a subset of these? If the latter, should a subset of inpatient locations be subject to such a requirement? What would be the potential value and burden trade-offs to facilities? And, should any requirement specify that reporting also be to CDC’s NSSP (in addition to more general reporting to state/local syndromic surveillance systems? (noting that often the reporting to CDC’s NSSP happens through a given state/local system and that applicable law may apply).

- How can CMS leverage its authorities and programs to improve the quality of data reported to CDC’s NSSP, especially for key elements that are sometimes incomplete, including discharge diagnoses, discharge disposition, and patient class?⁸⁴¹

- In addition to its value for public health, how could CDC’s NSSP serve as a tool to directly improve clinical practice, patient safety, and overall situational awareness? What types of questions would you like the system to help answer?

⁸⁴⁰ <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>

⁸⁴¹ <https://www.cdc.gov/nssp/technical-pubs-and-standards.html#Dictionaries>

XI. MedPAC Recommendations and Publicly Available Files

A. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2024 "Report to the Congress: Medicare Payment Policy" and have given the recommendations in the report consideration in conjunction with the policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2025 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653-7226, or visit MedPAC's website at <https://www.medpac.gov>.