DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-25-05-Hospitals/CAHs

DATE: **October 22, 2024**

TO: CMS Locations, State Agencies, Hospitals/CAHs, and other stakeholders

FROM: Directors, Quality, Safety & Oversight Group (QSOG), and Survey & Operations Group (SOG)

SUBJECT: Updates to the Condition of Participation (CoP) Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report Acute Respiratory Illnesses

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities have appropriate insight related to evolving infection prevention and control needs.
- CMS has released new regulatory requirements for all hospitals and critical access hospitals (CAHs) at 42 C.F.R. §§482.42(e) and 485.640(d), respectively, to report information in accordance with a frequency and standardized format, as specified by the Secretary.
- Failure to report the specified data related to COVID-19, influenza, and respiratory syncytial virus (RSV), including confirmed infections of respiratory illnesses 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, may lead to the termination of a hospital's participation from the Medicare and Medicaid programs.

Background

On August 28, 2024, CMS published revisions to the Condition of Participation (CoP) requirements for hospitals and CAHs to report acute respiratory illnesses in the *Medicare and Medicaid Programs and the Children's Health Insurance 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 2025 Rates; Quality Programs Requirements; and Other Policy Changes* (CMS-1808-F) Final Rule in the Federal Register (89 FR 68986).

This rule finalized hospital and CAH CoP requirements for ongoing respiratory illness reporting in a modified form, as proposed. Hospitals and CAHs, in a standardized format and frequency

specified by the Secretary, must electronically report data related to acute respiratory illnesses, including SARS-CoV2/COVID-19, influenza, and RSV, including confirmed infections of respiratory illnesses 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. Beginning November 1, 2024, hospitals and CAHs must electronically report this information to CDC's National Healthcare Safety Network (NHSN) or other CDC-owned or CDC-supported system, as determined by the Secretary.

This rule also finalized requirements for additional data reporting during a declared national, state, or local public health emergency (PHE) for an acute infectious illness. During a declared national, state, or local PHE for an acute infectious illness, the hospital and CAH must also electronically report data elements including facility structure and infrastructure operational status including hospital/ED diversion status, staffing shortages, supply inventory shortages (for example, equipment, blood products, gases), and relevant medical countermeasures and therapeutics (or both).

Discussion

The reporting requirements referenced and described herein are applicable to all Medicare- and Medicaid-participating hospitals and CAHs, to ensure that healthcare facilities have appropriate insight into their evolving infection prevention and control needs, particularly for respiratory illnesses. The requirement to collect this data and transmit them will also encourage greater awareness and promotion of best practices in infection prevention and control within these facilities. A streamlined approach to reporting data will greatly assist HHS in tracking the movement of respiratory infections and identifying potential strains in the healthcare delivery system. The completeness, accuracy, and timeliness of the data will inform HHS' decisions to address capacity and resource needs to ensure a fully coordinated effort across the nation. As with any CoP, if a hospital or CAH fails to consistently report as required, CMS may determine the provider to be non-compliant with the hospital or the CAH CoPs set forth at §§ 482.42(e) and 485.640(d), respectively, and the provider may be subject to termination pursuant to 42 CFR 489.53(a)(3).

Data Reporting Elements and Reporting Mechanisms

Beginning November 1, 2024, hospitals and CAHs must electronically report data on acute respiratory illnesses to include COVID-19, influenza, and RSV, to the CDC's NHSN (or other CDC-owned or CDC supported system, as determined by the Secretary). All hospitals and CAHs (except Psychiatric Hospitals, Rehabilitation Hospitals, Psychiatric Hospital Distinct Part Units, and Rehabilitation Hospital Distinct Part Units) must submit daily data values on a weekly basis to NHSN. The weekly data submission should be submitted by Tuesday 11:59 pm PT and include daily data for each day of the previous week, defined as the previous Sunday through Saturday.

However, in response to public comments in the final rule, we are providing a second process for reporting data elements under certain conditions. Specifically, for new admissions of patients with confirmed respiratory illnesses, including COVID-19, influenza, and RSV by age group, hospitals would report this data as weekly totals instead of providing daily data values. We further clarified that the other data elements, such as staffed bed capacity and occupancy, prevalence of hospitalizations and ICU patients by respiratory illnesses, required under this provision would be reported as one-day-a-week snapshots. Therefore, this new model of reporting discussed in the rule—one-day-a-week snapshots and weekly total new hospital admissions—provides hospitals and CAHs a new pathway for weekly reporting.

As discussed in the final rule (https://www.federalregister.gov/d/2024-17021/p-8188, 89 FR 69888), we believe our approach of totals where most important/impactful, and snapshots where feasible, strikes an appropriate balance between value/burden, particularly since the overall impact of shifting to weekly totals and snapshots reporting already represents a significant reduction in burden relative to the proposed rule, which involved reporting daily totals on a weekly basis. Changes may be made over time based on patient and population health needs and technology advances, but for FY 2025, the information collection will include:

One-Day-a-Week Snapshot	Weekly Total New Hospital Admissions
• Staffed bed capacity and occupancy including adult and pediatric • Hospitalizations prevalence by respiratory illness and bed type	• Total new hospital admissions for adult and pediatric patients by age range, over a defined weekly period

As noted, providers still have the option to report daily data values weekly as they did before. For more details on these two options/pathways for reporting, please see the CDC NHSN Hospital Respiratory Illness Data protocol at NHSN Hospital Respiratory Data (HRD) Reporting (cdc.gov).

Psychiatric Hospitals, Rehabilitation Hospitals, Psychiatric Hospital Distinct Part Units, and Rehabilitation Hospital Distinct Part Units will report once, annually, beginning in January, and only include the data for the previous week. For additional information on respiratory illness data reporting elements and reporting mechanisms, please visit Hospital Respiratory Data | NHSN | CDC.

Facilities to Report

The following hospitals should report the required data at the cadence specified in the table below.

Reporting Cadence	Facility description
Weekly	• Short-term Acute Care Hospitals (including Medicaid-Only Short-term Acute Care Hospitals) • Long-term Care Hospitals (LTCHs) • Critical Access Hospitals (CAHs) • Indian Health Service Hospitals • Children's Hospitals (including Medicaid-Only Children's Hospitals) • Cancer Hospitals
Annually[1] *(January)*	• Psychiatric Hospitals (including Medicaid-Only Psychiatric Hospitals) • Rehabilitation Hospitals (including Medicaid-Only Rehabilitation Hospitals)

[1] Under the hospital and CAH COVID-19 reporting requirements that were in effect from September 2, 2020, through April 30, 2024, the Secretary determined the reporting frequency for psychiatric and rehabilitation hospitals was to be on an annual basis. This annual reporting frequency has been applied through this guidance to psychiatric and rehabilitation distinct part units (DPUs) due to the similarities (evidenced by average patient admissions data) between these types of DPUs and psychiatric and rehabilitation hospitals.

	• Psychiatric Hospital Distinct Part Units • Rehabilitation Hospital Distinct Part Units

Reporting Timing

The weekly data submission should be submitted by Tuesday 11:59 pm PT and include data for the previous week, defined as the previous Sunday through Saturday for both reporting pathways/options discussed above (i.e., whichever weekly reporting pathway the hospital chooses to use—the one-day-a-week snapshots and weekly total new hospital admissions pathway or the daily data pathway. Psychiatric Hospitals (including Medicaid-Only Psychiatric Hospitals), Rehabilitation Hospitals (including Medicaid-Only Rehabilitation Hospitals), Psychiatric Hospital Distinct Part Units, and Rehabilitation Hospital Distinct Part Units will report once, annually, in January and only include the data for the previous week.

Enforcement Process for Incomplete Reporting and Non-compliance

CMS will review reporting submissions in 28-day increments, or four total reporting weeks. The CDC will evaluate for completeness and timeliness the reporting on a weekly basis and will provide CMS with final reports generated following the submission deadline in the fourth week of the period. CMS has established a multi-step approach to notification and enforcement for incomplete reporting of the specified data elements on a weekly basis and non-compliance with the hospital and CAH reporting requirements implemented in the FY 2025 IPPS Final Rule. Hospitals or CAHs that fail to report the specified data elements on a weekly basis will receive an incomplete reporting notification letter from CMS. Continued noncompliance with reporting requirements may result in future enforcement action for the provider, including CMS determining the provider to be non-compliant with the hospital or the CAH CoPs set forth at §§ 482.42(e) and 485.640(d), respectively, and the provider being subject to termination pursuant to 42 CFR 489.53(a)(3).

Compliance with these reporting requirements will be determined by CMS independently from health and safety surveys for all other CoPs performed by state survey agencies or accreditation organizations processes under 42 CFR Part 488.

Steps in Enforcement Process for Failure to Report

1. *The reporting requirements are effective November 1, 2024. Providers who have not demonstrated complete reporting, as determined by CMS, for the first 28-day reporting period (i.e., not reporting the specified elements on a weekly basis for the 28-day period) will receive a warning letter ("Initial Warning Letter"), after this initial 28-day period, outlining the hospital/CAH respiratory illness reporting requirements, reporting options, and the CDC contact information for technical assistance.* ***This initial incomplete reporting warning letter will only be sent to providers that have not demonstrated complete reporting of the data elements for this first 28-day reporting period in November 2024 and will not be issued after this period. This letter is not part of the incomplete reporting notification letters described in steps 2 through 5 here.***
2. *The first incomplete reporting notification letter will begin following a 28-day period of incomplete reporting as determined by CMS ("First Warning Letter"). Providers*

will have the next 28-day period to demonstrate complete reporting of the specified data elements on a weekly basis for this period.

3. *Providers failing to demonstrate complete reporting of the specified data elements on a weekly basis for the 28-day reporting period following the first incomplete reporting notification letter will receive a second incomplete reporting notification letter ("Second Warning Letter"). This notification letter will indicate that the provider will have the next 28-day reporting period to demonstrate complete reporting of the specified data elements on a weekly basis for this period.*
4. *Providers failing to demonstrate complete reporting of the specified data elements on a weekly basis for the 28-day reporting period following the second incomplete reporting notification letter will receive a third incomplete reporting notification letter ("Third Warning Letter"). This notification letter will indicate that the provider will have the next 28-day reporting period to demonstrate complete reporting of the specified data elements on a weekly basis for this period, otherwise the provider will receive the fourth and final incomplete reporting notification letter, as noted in step 5.*
5. *Providers failing to demonstrate complete reporting of the specified data elements on a weekly basis for the 28-day reporting period following the third incomplete reporting notification letter will receive a fourth and final incomplete reporting notification letter ("Final Warning Letter"). This letter will include a notification to the provider that failure to demonstrate complete reporting of the specified data elements within 30 days from the date of this fourth and final notification letter may result in an enforcement action and possible termination of the Medicare provider agreement for the hospital or CAH.*

This incomplete reporting notification and enforcement process is effective November 1, 2024, and will be ongoing thereafter.

Providers that proceed to termination for failure to demonstrate compliance with the regulatory reporting requirements will have a right to appeal the determination under 42 CFR part 498, as with any other termination action. Additionally, providers terminated only for failure to report will be subject to a 30-day reasonable assurance period under 42 CFR 489.57, if the provider submits a new application for initial certification to participate in Medicare as a certified provider. Regulatory requirements at 42 CFR 455.416 direct State Medicaid Agencies to deny or terminate enrollment of any Medicaid or CHIP provider who is terminated from the Medicare program.

As we recognize that there may be issues with the transmission of data or meeting the data reporting requirements, hospitals and CAHs that receive notification of incomplete reporting will have an opportunity to provide evidence of complete reporting. A provider may submit evidence to CDC within 5 business days of receiving an incomplete reporting notification letter. CDC will notify CMS that the provider has submitted complete data to NHSN. CMS will then determine if the provider is compliant with the reporting requirements and will adjust the incomplete reporting notification letters accordingly.

Once CMS determines a hospital or CAH is in compliance with the reporting requirements, the incomplete reporting notification letter process will stop. If a hospital or CAH then subsequently demonstrates incomplete reporting in the future, a new incomplete reporting notification letter process will begin.

If you believe an incomplete reporting notification letter is the result of a technical error, please contact the CDC at NHSN@cdc.gov and use the following subject line: "Hospital Respiratory Illness compliance."

We also recommend reviewing the resources CDC has posted at Hospital Respiratory Data | NHSN | CDC

Contact:
For any changes to hospital points of contact or hospital information, or questions regarding the Steps in Enforcement Process for Failure to Report, please contact: QSOG_Hospital@cms.hhs.gov.

For questions, technical assistance, or guidance on how to report data, please contact CDC at NHSN@cdc.gov; or for additional information and resources on respiratory illness reporting requirements, please visit Hospital Respiratory Data | NHSN | CDC.

Effective Date:
Immediately. This policy should be communicated with all survey and certification staff, their managers, and the CMS Location training coordinators of this memorandum.

/s/

Karen L. Tritz
Director, Survey & Operations Group

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Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15-minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

Get guidance memos issued by the Quality, Safety and Oversight Group by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.