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-21-03-Hospitals/CAHs

DATE: **October 6, 2020**

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

FROM: Director Quality, Safety & Oversight Group- Division of Continuing and Acute Care Providers

SUBJECT: Interim Final Rule (IFC), CMS-3401-IFC; Requirements and Enforcement Process for Reporting of COVID-19 Data Elements for Hospitals and Critical Access Hospitals

Memorandum Summary

- CMS is committed to continuing to take critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On September 2, 2020, the Federal Register published an interim final rule with comment period (IFC) (85 FR 54820).
- 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 in a standardized format as specified by the Secretary during the PHE for COVID-19.
- Failure to report the specified data needed to support broader surveillance of COVID-19 may lead to the imposition of the remedy to terminate a provider's participation from the Medicare and Medicaid programs.

Background

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 healthcare facility staff as appropriate about the presence of a person under investigation for COVID-19.[1]

On September 2, 2020, The Federal Register published CMS's interim final rule (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," CMS-3401-IFC, which included new requirements for hospitals and CAHs to report data in accordance with a frequency and in a standardized format as specified by the Secretary during the PHE for COVID-19. The regulatory requirements for hospitals and CAHs can be found at 42 CFR §§ 482.42(e) and 485.640(d) respectively (see 85 FR 54873). These reporting requirements support our responsibility to

[1] https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2

protect the health and safety of hospital and CAH patients. This data allows CMS to monitor whether individual hospitals and CAHs are appropriately tracking, responding to, and mitigating the spread and impact of COVID-19 on patients, the staff who care for them, and the general public.

Discussion

The reporting requirements described herein are applicable to all Medicare and Medicaid hospitals and CAHs, as infection prevention and control is, and continues to be, a primary goal during the PHE for COVID-19. The requirement to collect these 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 the White House Coronavirus Task Force (COVID-19 Task Force) in tracking the movement of the virus and identifying potential strains in the healthcare delivery system. The completeness, accuracy, and timeliness of the data will inform the COVID-19 Task Force decisions to address capacity and resource needs to ensure a fully coordinated effort across the nation. As noted in the IFC, if a hospital or CAH fails to consistently report test results throughout the duration of the PHE for COVID-19, CMS will 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 will be subject to termination pursuant to 42 CFR 489.53(a)(3).

Data Reporting Elements and Reporting Mechanisms

On July 29, 2020, HHS published updated guidance for hospital COVID-19 reporting: https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf. The guidance states that hospitals should report specified information at least once daily through one of the prescribed methods described below.

Facilities to Report

The following hospitals should report the data elements specified in the table below on a daily basis, except Psychiatric and Rehabilitation hospitals will report weekly:

- Short term
- Long term
- Critical access hospital
- Children's
- Distinct part psychiatric hospital
- Medicaid only short term
- Medicaid only children's,
- Medicaid only long-term hospitals

Reporting Timing

Reporting should be completed within one business day of the reporting period. If a hospital does not have the ability to report on weekends or holidays, the data can be submitted on the next business day.

Data Elements (See Guidance for Hospital Reporting and FAQ for definitions)

All fields are required except as noted below (IDs 25, 28, 32, 33-38 are optional with 33 – 38 becoming mandatory in the coming weeks. Additional information will be provided).

ID	Information Needed	Definition
Items 1 – 25 are to be reported daily (except psychiatric and rehabilitation hospitals who are to report these weekly)		
1.	Hospital information (in separate fields) a) Hospital name b) CCN c) OrgID (Optional) d) State e) County f) ZIP g) TeleTracking ID (Optional)	Provide the information about the hospital (in separate fields) • Name of hospital • Hospital CMS Certification Number (CCN) • NHSN OrgID (Optional) • State where the hospital is located • County where the hospital is located • ZIP where the hospital is located • The identifier assigned by TeleTracking (Optional)
2.	a) All hospital beds Subset: b) All adult hospital beds	Total number of all staffed inpatient and outpatient beds in your hospital, including all overflow, observation, and active surge/expansion beds used for inpatients and for outpatients (includes all ICU, ED, and observation). Total number of all staffed inpatient and outpatient adult beds in your hospital, including all overflow and active surge/expansion beds for inpatients and for outpatients (includes all ICU, ED, and observation).
3.	a) All hospital inpatient beds Subset: b) Adult hospital inpatient beds	Total number of staffed inpatient beds in your hospital including all overflow, observation, and active surge/expansion beds used for inpatients (includes all ICU beds). This is a subset of #2. Total number of staffed inpatient adult beds in your hospital including all overflow and active surge/expansion beds used for inpatients (includes all designated ICU beds). This is also a subset of #2.
4.	a) All hospital inpatient bed occupancy Subset: b) Adult hospital inpatient bed occupancy	Total number of staffed inpatient beds that are occupied. Total number of staffed inpatient adult beds that are occupied.
5.	a) ICU beds	Total number of staffed inpatient ICU beds. This is a subset of #2 and #3.

	Subset: b) Adult ICU beds	Total number of staffed inpatient adult ICU beds. This is also a subset of #2 and #3.
6.	a) ICU bed occupancy Subset: b) Adult ICU bed occupancy	Total number of staffed inpatient ICU beds that are occupied. This is a subset of #4. Total number of staffed inpatient adult ICU beds that are occupied. This is also a subset of #4.
7.	Total mechanical ventilators	Enter the total number (in use and not in use) of all mechanical ventilators, including adult, pediatric, neonatal ventilators, anesthesia machines and portable/transport ventilators available in the facility. Include BiPAP machines if the hospital uses BiPAP to deliver positive pressure ventilation via artificial airways.
8.	Mechanical ventilators in use	Enter the total number of mechanical ventilators in use at the time the data is collected, including adult, pediatric, neonatal ventilators, anesthesia machines and portable/transport ventilators. Include BiPAP machines if the hospital uses BiPAP to deliver positive pressure ventilation via artificial airways.
9.	a) Total hospitalized adult suspected or confirmed positive COVID patients Subset: b) Hospitalized adult confirmed-positive COVID patients	Patients currently hospitalized in an adult inpatient bed who have laboratory-confirmed or suspected COVID-19. Include those in observation beds. Patients currently hospitalized in an adult inpatient bed who have laboratory-confirmed COVID-19. Include those in observation beds. Include patients who have both laboratory-confirmed COVID-19 and laboratory-confirmed influenza in this field.
10.	a) Total hospitalized pediatric suspected or confirmed positive COVID patients Subset: b) Hospitalized pediatric confirmed-positive COVID patients	Patients currently hospitalized in a pediatric inpatient bed, including NICU, PICU, newborn, and nursery, who are suspected or laboratory-confirmed-positive for COVID-19. Include those in observation beds. Patients currently hospitalized in a pediatric inpatient bed, including NICU, PICU, newborn, and nursery, who have laboratory-confirmed COVID-19. Include those in observation beds. Include patients who have both laboratory-confirmed COVID-19 and laboratory-confirmed influenza in this field.
11.	Hospitalized and ventilated COVID patients	Patients currently hospitalized in an adult, pediatric or neonatal inpatient bed who have suspected or

		laboratory-confirmed COVID-19 and are on a mechanical ventilator (as defined in #7 above).
12.	a) Total ICU adult suspected or confirmed positive COVID patients Subset: b) Hospitalized ICU adult confirmed-positive COVID patients	Patients currently hospitalized in a designated adult ICU bed who have suspected or laboratory-confirmed COVID-19. Patients currently hospitalized in a designated adult ICU bed who have laboratory-confirmed COVID-19. Include patients who have both laboratory-confirmed COVID-19 and laboratory-confirmed influenza in this field.
13.	Hospital onset	Total current inpatients with onset of suspected or laboratory-confirmed COVID-19 fourteen or more days after admission for a condition other than COVID-19.
14.	ED/overflow	Patients with suspected or laboratory-confirmed COVID-19 who currently are in the Emergency Department (ED) or any overflow location awaiting an inpatient bed.
15.	ED/overflow and ventilated	Patients with suspected or laboratory-confirmed COVID-19 who currently are in the ED or any overflow location awaiting an inpatient bed and on a mechanical ventilator. This is a subset of #14.
16.	Previous day's COVID-19 Deaths	Number of patients with suspected or laboratory-confirmed COVID-19 who died on the previous calendar day in the hospital, ED, or any overflow location. Include patients who have both laboratory-confirmed COVID-19 and laboratory-confirmed influenza in this field.
17.	Previous day's adult admissions: a) Previous day's adult admissions with confirmed COVID-19 and breakdown by age bracket:	Enter the number of patients who were admitted to an adult inpatient bed on the previous calendar day who had confirmed COVID-19 at the time of admission. This is a subset of #9. As a subset, provide the breakdown by age bracket: 18-19 20-29 30-39 40-49 50-59 60-69 70-79 80+

	b) Previous day's adult admissions with suspected COVID-19 and breakdown by age bracket:	Unknown Enter the number of patients who were admitted to an adult inpatient bed on the previous calendar day who had suspected COVID-19 at the time of admission. This is a subset of #9. As a subset, provide the breakdown by age bracket: 18-19 20-29 30-39 40-49 50-59 60-69 70-79 80+ Unknown
18.	Previous day's pediatric COVID-19 admissions: a) Previous day's pediatric admissions with confirmed COVID-19: b) Previous day's pediatric admissions with suspected COVID-19	 Enter the number of pediatric patients who were admitted to an inpatient bed, including NICU, PICU, newborn, and nursery, on the previous calendar day who had confirmed COVID-19 at the time of admission. This is a subset of #10. Enter the number of pediatrics patients who were admitted to an inpatient bed, including NICU, PICU, newborn, and nursery, on the previous calendar day who had suspected COVID-19 at the time of admission. This is a subset of #10.
19.	Previous day's total ED visits	Enter the total number of patient visits to the ED who were seen on the previous calendar day regardless of reason for visit. Include all patients who are triaged even if they leave before being seen by a provider.
20.	Previous day's total COVID-19-related ED visits	Enter the total number of ED visits who were seen on the previous calendar day who had a visit related to COVID-19 (meets suspected or confirmed definition or presents for COVID diagnostic testing – do not count patients who present for pre-procedure screening).
21.	Previous day's remdesivir used (Required until November 4th and then Optional)	Enter the number of remdesivir vials used on the previous calendar day in an inpatient, ED, and/or overflow location
22.	Current inventory of Remdesivir (Required until November 4th and then Optional)	Enter the number of remdesivir vials in inventory at 11:59pm on the previous calendar day in the hospital pharmacy

23.	Critical staffing shortage today (Y/N) (Required until November 4th and then Optional)	Enter Y if you have a critical staffing shortage today. Enter N if you do not have a staffing shortage today. If you do not report this value, the default is N. If you have a shortage, report this daily until the shortage is resolved. Each facility should identify staffing shortages based on their facility needs and internal policies for staffing ratios. The use of temporary staff does not count as a staffing shortage if staffing ratios are met according to the facility's needs and internal policies for staffing ratios. (Environmental services, nurses, respiratory therapists, pharmacists and pharmacy technicians, physicians, other licensed independent practitioners, temporary physicians, nurses, respiratory therapists, and pharmacists, phlebotomists, other critical healthcare personnel).
24.	Critical staffing shortage anticipated within a week (Y/N) (Required until November 4th and then Optional)	Enter Y if you anticipate a critical staffing shortage within a week. Enter N if you do not anticipate a staffing shortage within a week. If you do not report this value, the default is N. If you have a shortage, report this daily until the shortage is resolved. Each facility should identify staffing shortages based on their facility needs and internal policies for staffing ratios. The use of temporary staff does not count as a staffing shortage if staffing ratios are met according to the facility's needs and internal policies for staffing ratios.
25.	Staffing shortage details (Optional)	If Y to #23 or #24, specify type of shortage (Environmental services, nurses, respiratory therapists, pharmacists and pharmacy technicians, physicians, other licensed independent practitioners, temporary physicians, nurses, respiratory therapists, and pharmacists, phlebotomists, other critical healthcare personnel).
For items 26 – 32, report one time a week on Wednesday		
26.	Are your PPE supply items managed (purchased, allocated, and/or stored) at the facility level or, if you are part of a	Check the response below which reflects the management of PPE for your facility (including purchasing, allocation, and/or storage).

	health system, at the health system level (or other multiple facility group)? (SYSTEM or FACILITY)	• Health system level or multiple-hospital group (e.g., PPE purchased at the health system level, par levels managed centrally, in stock supply available at another system location such as a central warehouse). Enter SYSTEM for this choice. • Facility level (e.g., PPE purchased by your individual facility, par levels managed at the facility-level, in stock supply is all on-site). Enter FACILITY for this choice.
27.	On hand supply (DURATION IN DAYS) a) Ventilator supplies b) N95 respirators c) Surgical and procedure masks d) Eye protection including face shields and goggles e) Single-use gowns f) Exam gloves (sterile and non-sterile)	Provide calculated range of days of supply in stock for ventilator supplies and each PPE category. For supply categories that may have varying quantities, days on hand, or ability to obtain and maintain, reply for the item that has the lowest stock on hand. • 0 days • 1-3 days • 4-6 days • 7-14 days • 15-30 days • >30 days Calculation may be provided by your hospital's ERP system or by utilizing the CDC's PPE burn rate calculator assumptions*: • Ventilator supplies (any supplies, including flow sensors, tubing, connectors, valves, filters, etc.) • N95 respirators • Surgical masks • Eye protection including face shields and goggles • Single-use gowns • Exam gloves
28.	On hand supply (INDIVIDUAL UNITS/"EACHES"): (Optional) a) N95 respirators b) Other respirators such as PAPRs or elastomerics c) Surgical and procedure masks d) Eye protection including face shields and goggles e) Single-use gowns	Please report this information **if feasible**. For each listed supply item below, record the number of individual units (or "eaches") available in the facility on the date of data collection. For hospitals that are a part of a health system, do NOT include supplies at other system locations, including warehouses. • N95 respirators • Other respirators such as PAPRs or elastomerics • Surgical masks • Eye protection including face shields and goggles • Single-use gowns

	f) Launderable gowns g) Exam gloves (single)	• Reusable/launderable gowns • Exam gloves (single) Information can be obtained from materials management, infection prevention leader, operational leadership, or the COVID-19 incident command leadership in your facility.
29.	Are you able to obtain these items? (Y/N/NA) a) Ventilator supplies (any supplies excluding medications) b) Ventilator medications c) N95 respirators d) Other respirators such as PAPRs or elastomerics e) Surgical and procedure masks f) Eye protection including face shields and goggles g) Single-use gowns h) Exam gloves i) Are you able to maintain a supply of launderable gowns?	Select YES for each of the supply types that your facility is able to order and obtain. If you have placed an order but are not able to have that order filled, please answer NO. Enter N/A if item is not applicable at the facility. • Ventilator supplies (any supplies, including flow sensors, tubing, connectors, valves, filters, etc.) • Ventilator medications • N95 respirators • Other respirators such as PAPRs or elastomerics • Surgical masks • Eye protection including face shields and goggles • Single-use gowns • Exam gloves Information can be obtained from materials management, infection prevention leader, operational leadership, or the COVID-19 incidence command leadership in your facility.
30.	Are you able to maintain at least a 3-day supply of these items? (Y/N/NA) a) Ventilator supplies (any supplies excluding medications) b) Ventilator medications c) N95 respirators d) Other respirators such as PAPRs or elastomerics e) Surgical and procedure masks f) Eye protection including face shields and goggles g) Single-use gowns h) Exam Gloves	Enter YES for each supply type for which your facility is able to maintain at least a 3-day supply. Enter NO for those supply types your facility is not able to maintain at least a 3-day supply. Enter N/A if the item is not applicable for your facility. • Ventilator supplies (any supplies, including flow sensors, tubing, connectors, valves, filters, etc.) • Ventilator medications • N95 respirators • Other respirators such as PAPRs or elastomerics • Surgical masks • Eye protection including face shields and goggles • Single-use gowns • Exam Gloves • Laboratory – nasal pharyngeal swabs? • Laboratory – nasal swabs

	i) Laboratory – nasal pharyngeal swabs j) Laboratory – nasal swabs k) Laboratory – viral transport media	• Laboratory – viral transport media
31.	Does your facility re-use or extend the use of PPE? a) Reusable/launderable isolation gowns b) PAPRs or elastomerics c) N95 respirators	Enter YES for each supply type your facility re-uses or extends use of. Enter NO for those supply types your facility does not re-use or extend use of. Enter N/A if the item is not applicable for your facility.
32.	Indicate any specific or critical medical supplies or medication shortages you are currently experiencing or anticipate experiencing in the next three days. (Optional)	Free text entry
Influenza fields 33 - 37 to be reported every day except for psychiatric and rehabilitation hospitals who report weekly – Optional starting 10/19/20 and with the intention to have them mandatory in the coming weeks. Additional information will be provided at that time. Existing upload templates will continue to work during transition. Laboratory confirmation includes detection of influenza virus through molecular tests (e.g., polymerase chain reaction, nucleic acid amplification), antigen detection tests, immunofluorescence tests, and virus culture.		
33.	Total hospitalized patients with laboratory-confirmed influenza	Patients (all ages) currently hospitalized in an inpatient bed who have laboratory-confirmed influenza. Include those in observation beds.
34.	Previous day's influenza admissions	Enter the number of patients (all ages) who were admitted to an inpatient bed on the previous calendar day who had laboratory-confirmed influenza at the time of admission. This is a subset of #33.
35.	Total ICU patients with laboratory-confirmed influenza	Patients (all ages) currently hospitalized in a designated ICU bed with laboratory-confirmed influenza. This is a subset of #33.
36.	Total hospitalized patients with both laboratory-confirmed COVID-19 and influenza	Patients (all ages) currently hospitalized in an inpatient bed who have laboratory-confirmed COVID-19 and laboratory-confirmed influenza. This is a subset of #9b/10b and #33.
37.	Previous day's influenza deaths	Number of patients with laboratory-confirmed influenza who died on the previous calendar day in the hospital, ED, or any overflow location.
38.	Previous day's deaths with both COVID-19 and influenza	Number of patients with laboratory-confirmed influenza AND laboratory-confirmed COVID-19 who died on the previous calendar day in the

		hospital, ED, or any overflow location. This is a subset of #16,

Enforcement Process for Non-compliance

CMS has established a multi-step approach to enforcement for non-compliance with the hospital and CAH reporting requirements implemented in the September 2, 2020 IFC. Hospitals or CAHs that fail to report the specified data elements on a daily basis will receive a notification from their CMS Location of their noncompliance with the reporting requirements and any further noncompliance with reporting requirements may result in future enforcement actions. Compliance with these reporting requirements will be determined 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. Hospitals and CAHs that do not meet the reporting requirements completely on a daily basis will receive an initial notification from CMS. This notification of non-compliance will also serve as a reminder of the reporting requirements.
2. Three weeks after receiving an initial notification of noncompliance with reporting requirements, those providers that continue not to submit the specified information daily and completely will receive a second reminder notification of their failure to meet the reporting requirements and that future enforcement actions will be taken for continued noncompliance, which may result in termination of the Medicare provider agreement.
3. Those providers that have continually failed to meet the reporting requirements for a period of six weeks after receiving an initial notification will receive the first in a series of enforcement notification letters. At this point, the enforcement actions are now in process and providers will have 1 calendar week to demonstrate compliance.
4. Providers failing to meet the reporting requirements within 1 calendar week following the first enforcement notification letter will receive a second enforcement notification letter and third enforcement letter, if non-compliant the following week. The third letter will indicate that that the provider will have 1 calendar week to demonstrate compliance with the reporting requirements otherwise the provider will receive a fourth and final enforcement notification letter, as noted in step 5.
5. Providers that have failed to meet the reporting requirements within 1 week following the third enforcement notification letter will receive a fourth and final enforcement notification letter. This notification will include a notice of termination to become effective within 30 days from the date of the notification. Failure to meet the reporting requirements within this 30-day timeframe may result in termination of the Medicare provider agreement.

This enforcement process will be ongoing throughout the PHE. Steps 1-2 of the enforcement process are only applicable from October 7- November 18, 2020. For non-compliance identified after this time period, the series of enforcement notifications described in steps 3–5 above will begin immediately.

Providers that proceed to termination for failure to demonstrate compliance with the regulatory reporting requirements or failure to work with the HHS Data and Products Team (HHS Team) to reach compliance will have a right appeal the determination under 42 CFR part 498, as with any other termination actions. Additionally, providers terminated for failure to report will be subject to a 30 day reasonable assurance period under 42 CFR 489.57, if the provider submits an

application 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 requirement, if hospitals and CAHs have received notification of non-compliance, providers will have an opportunity to provide evidence of compliance. A provider may submit evidence to CMS within 72 hours of receiving notification of non-compliance. If the hospital or CAH is found to be in compliance with the reporting requirements, enforcement remedies will be rescinded. If the enforcement action for failure to report is rescinded and the provider subsequently demonstrates non-compliance with the requirements in the future, a new enforcement action will begin.

Additionally, hospitals and CAHs have an opportunity to work with the HHS Team to develop a plan for meeting reporting requirements. Hospitals and CAHs may contact the HHS Protect Service Desk. If the hospital or CAH has made arrangements for reporting with the HHS Team, CMS will receive this information from HHS and will suspend for 30 days further enforcement actions for reporting requirements.

Contact: QSOG_Hospital@cms.hhs.gov

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/
David R. Wright

cc: Survey & Operations Group Management