DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Quality Safety & Oversight Group

CMS Certification Number: [CCN]

[Notice Date]

Sent Via Quality Improvement and Evaluation System (QIES) Provider Mailbox

[Administrator] [Facility Name] [Facility Address]

Dear Administrator:

SUBJECT: COVID-19 Reporting

2019 NOVEL CORONAVIRUS (COVID-19) REPORTING REQUIREMENTS

The Centers for Medicare & Medicaid Services (CMS) is committed to taking critical steps to ensure America's health care facilities are prepared to respond to the threat of COVID-19. On August 25, 2020, CMS released an Interim Final Rule Comment (IFC), announcing that in accordance with 42 CFR § 482.42(e) and 485.640(d), hospitals and Critical Access Hospitals (CAHs) are required to report information on COVID-19 in accordance with a frequency and in a standardized format as specified by the Secretary during the Public Health Emergency (PHE) for COVID-19 (https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf) through one of the approved reporting methods to ensure appropriate tracking, response, and mitigation of COVID-19 in hospitals.

For providers to demonstrate compliance with the new requirement, facilities must submit the data to one of the approved methods at least once daily. For additional information on COVID-19 reporting requirements please visit: https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf.

This letter provides you with your reporting status based upon the information provided to CMS, through HHS, in order for you to correct your data submission or identify submission problems prior to beginning enforcement. Non-compliance is assessed based upon a one-week reporting period. As of October 5th, 2020, a preliminary analysis showed that this facility did not meet the requirements for the reporting period of September 25th to October 1st. Review the fields listed below and ensure that this facility is reporting all of the fields for all seven days, including weekends, within one business day. If you feel this preliminary status is an error, please contact the HHS Protect Service Desk (Protect-ServiceDesk@hhs.gov) in order to fix any data

transmission or other errors. You will receive a second letter outlining your status in approximately 3 weeks.

As a reminder for the providers listed below, there are 3 opportunities for reporting: through the State reporting system, direct reporting into TeleTracking, or authorizing your health IT vendor or other third-party to share information directly with HHS Protect. These providers should refer to https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf for the current list of data items specified and mechanisms for reporting.

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

Please see the table below for the required data elements that must be reported to meet the completeness requirements (See Guidance for Hospital Reporting and FAQ for definitions):

Reported Daily, Including Weekends	Reported Once Weekly on Wednesday
Hospital Name	Are your PPE supply items managed (purchased,
	allocated, and/or stored) at the facility level or, if
	you are part of a health system, at the health
	system level (or other multiple facility group)?
Hospital CCN	On hand Supply in Days: Ventilator Supplies
Hospital OrgID (preferred but not required)	On hand Supply in Days: N95 Respirators
Hospital State	On hand Supply in Days: Surgical and Procedure
	Masks
Hospital County	On hand Supply in Days: Eye Protection
	Including Face Shields and Goggles
Hospital ZIP	On hand Supply in Days: Single Use Gowns
All Hospital Beds	On hand Supply in Days: Exam Gloves
All Adult Hospital Beds	Are you able to obtain: Ventilator Supplies
All Hospital Inpatient Beds	Are you able to obtain: Ventilator Medications
Adult Hospital Inpatient Beds	Are you able to obtain: N95 Respirators
All Hospital Inpatient Bed Occupancy	Are you able to obtain: Other respirators such as
	PAPRS or elastomerics
Adult Hospital Inpatient Bed Occupancy	Are you able to obtain: Surgical and Procedure
	Masks
ICU Beds	Are you able to obtain: Eye Protection Including
	Face Shields and Goggles
Adult ICU Beds	Are you able to obtain: Single Use Gowns
ICU Bed Occupancy	Are you able to obtain: Exam Gloves

Adult ICU Bed Occupancy	Are you able to maintain a supply of launderable gowns?
Total Mechanical Ventilators	Are you able to maintain a 3-day supply:
Total Mechanical Ventuators	Ventilator Supplies
Mechanical Ventilators in Use	Are you able to maintain a 3-day supply:
	Ventilator Medications
Total Hospitalized Adult Suspected or Confirmed	Are you able to maintain a 3-day supply: N95
Positive COVID Patients	Respirators
Hospitalized Adult Confirmed-Positive COVID	Are you able to maintain a 3-day supply: Other
Patients	respirators such as PAPRS or elastomerics
Total Hospitalized Pediatric Suspected or	Are you able to maintain a 3-day supply: Surgical
Confirmed Positive COVID Patients	and Procedure Masks
Hospitalized Pediatric Confirmed-Positive	Are you able to maintain a 3-day supply: Eye
COVID Patients	Protection Including Face Shields and Goggles
Hospitalized and Ventilated COVID Patients	Are you able to maintain a 3-day supply: Single
	Use Gowns
Total ICU adult suspected or confirmed positive	Are you able to maintain a 3-day supply: Exam
COVID patients	Gloves
Hospitalized ICU adult confirmed positive	Are you able to maintain a 3-day supply:
COVID patients	Laboratory nasopharyngeal swabs
Hospital Onset	Are you able to maintain a 3-day supply:
	Laboratory nasal swabs
ED Overflow	Are you able to maintain a 3-day supply:
	Laboratory viral transport media
ED Overflow and Ventilated	Does your facility re-use or extend the use of
D : D : D :	PPE: Reusable launderable gowns
Previous Day's Deaths	Does your facility re-use or extend the use of PPE: PAPRs or elastomerics
Previous Day's Adult Admissions Confirmed-	Does your facility re-use or extend the use of
Positive	PPE: N95 Masks
Previous Day's Adult Admissions Confirmed	
Positive Age Breakdown by Age Bracket	
Previous Day's Adult Admissions Suspected	
Previous Day's Adult Admissions Suspected Age	
Breakdown by Age Bracket	
Previous Day's Pediatric Admissions Confirmed	
Previous Day's Pediatric Admissions Suspected	
Previous Day's Total ED Visits Previous Day's Total COVID-19-Related ED	
Visits	
Previous Day's Remdesivir Used (Required until	
November 4 and then Optional)	
Current Inventory of Remdesivir (Required until	
November 4 and then Optional)	
Critical Staffing Shortage Today (Required until	
November 4 and then Optional)	
Critical Staffing Shortage Anticipated Within a	
Week (Required until November 4 and then	
Optional)	
Staffing Shortage Details (Optional)	
Starring Shortage Details (Optional)	

Total hospitalized patients with laboratory-	
confirmed influenza Optional starting	
10/19/20 with the intention to have these be	
mandatory fields within the coming weeks	
Previous day's influenza admissions Optional	
starting 10/19/20 with the intention to have	
these be mandatory fields within the coming	
weeks	
Total ICU patients with laboratory-confirmed	
influenza Optional starting 10/19/20 with the	
intention to have these be mandatory fields	
within the coming weeks	
Total hospitalized patients with both	
laboratory-confirmed COVID-19 and	
influenza Optional starting 10/19/20 with the	
intention to have these be mandatory fields	
within the coming weeks	
Previous day's influenza deaths Optional	
starting 10/19/20 with the intention to have	
these be mandatory fields within the coming	
weeks	
Previous day's influenza and COVID-19	
deaths Optional starting 10/19/20 with the	
intention to have these be mandatory fields	
within the coming weeks	

Beginning approximately October 21st, HHS will begin posting how many days each hospital reported the required data elements for the prior week. Please be sure to review your data to be sure you are reporting all of the required fields every day and contact <u>protect-servicedesk@hhs.gov</u> if you have any concerns. If you report through your state, verify with them that you are meeting the requirements.

CMS has established a multi-step approach to enforcement for non-compliance with the hospital and CAH reporting requirements following the September 2, 2020 interim final rule. Hospitals or CAHs that fail to report data elements in accordance with the <u>Guidance for Hospital Reporting</u> and <u>FAQ</u> will receive a notification from CMS of their non-compliance with the reporting requirements and any further non-compliance with reporting requirements may result in future enforcement actions. The determination of compliance will be done independent of the survey or accreditation processes under Part 488.

This letter is an initial notification from CMS that serves as a reminder of the reporting requirements. Three weeks following this notification, providers not meeting the reporting requirements under this regulation for the prior week will begin receiving their second notice of their status with respect to meeting the reporting requirements.

Three weeks after the second notice, analysis will evaluate the prior week's data reporting and continued non-compliance with the reporting requirement will result in providers receiving the first in the series of enforcement notifications. Providers failing to meet the reporting requirements one calendar week following the first enforcement notification will receive a

second enforcement notification. This notification will indicate that that the provider will have one calendar week to demonstrate compliance with the reporting requirements or the provider will receive the third and final enforcement notification. Lastly, providers with continued non-compliance one week after the third enforcement notification, a fourth and final notice will serve as the final enforcement notification to providers that have failed to meet the reporting requirements. This notification will include a notice of termination within 30 days from the date of the notification. Failure to meet the reporting requirements within this timeframe, will result in a termination of the Medicare provider agreement.

Hospitals and CAHs are encouraged to work with the HHS COVID-19 Response Team (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 further enforcement actions for reporting requirements for 30 days as long as the hospital or CAH continues working with the HHS Team to improve. Hospitals and CAHs who enter into a plan to improve and do not comply with weekly communication will be removed from suspension and will resume enforcement.

Providers that proceed to termination for failure to demonstrate compliance with the regulatory reporting requirements or failure to work with the HHS Team to reach compliance will have a right of appeal, as with any other termination actions. Providers terminated for failure to report will be subject to a 30-day reasonable assurance period following the termination of the Medicare provider agreement. Regulatory requirements at §455.416 direct State Medicaid Agencies to deny or terminate enrollment of any Medicaid or CHIP provider who is terminated from the Medicare program.

CMS does recognize that issues may arise 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 actions will be rescinded. If the enforcement action for failure to report is rescinded and the provider demonstrates future non-compliance with the requirements, a new enforcement action will begin.

If you have general questions regarding this notice, please submit your questions to QSOG_Hospital@cms.hhs.gov. If you need technical assistance or guidance on how to report, contact protect-servicedesk@hhs.gov.

Sincerely,

/s/

David Wright
Director, Quality, Safety & Oversight Group