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

Ref: QSO-20-29-NH

EXPIRED EFFECTIVE: December 31, 2024

DATE: June 6, 2025

ORIGINAL POSTING

DATE:

May 7, 2020

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: EXPIRED: Interim Final Rule Updating Requirements for

Notification of Confirmed and Suspected COVID-19 Cases

Among Residents and Staff in Nursing Homes

Memo Expiration Information:

Expiration Date:	December 31, 2024
Expiration	This memo was superseded by QSO-25-11-NH Long-Term
Information:	Care (LTC) Facility Acute Respiratory Illness Reporting
	Requirements released 12/21/2024. See OSO-25-11-NH for
	current requirements regarding respiratory illness
	reporting.

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On May 8, 2020, CMS will publish an interim final rule with comment period.
- **COVID-19 Reporting Requirements**: CMS is requiring nursing homes to report COVID-19 facility data to the Centers for Disease Control and Prevention (CDC) and to residents, their representatives, and families of residents in facilities.
- **Enforcement:** Failure to report in accordance with 42 CFR §483.80(g) can result in an enforcement action.
- **Updated Survey Tools:** CMS has updated the COVID-19 Focused Survey for Nursing Homes, Entrance Conference Worksheet, COVID-19 Focused Survey Protocol, and Summary of the COVID-19 Focused Survey for Nursing Homes to reflect COVID-19 reporting requirements.
- **COVID-19 Tags**: F884 and F885.
- Transparency: CMS will begin posting data from the CDC National Healthcare Safety Network (NHSN) for viewing by facilities, stakeholders, or the general public. The COVID-19 public use file will be available on https://data.cms.gov/.

Background

On April 19, 2020, CMS released memo QSO-20-26, "Upcoming Requirements for Notification of Confirmed COVID-19 (or COVID-19 Persons under Investigation) Among Residents and Staff in Nursing Homes," summarizing new facility reporting requirements that would soon be released through rulemaking.

On May 8, 2020, CMS will publish an interim final rule with comment period, titled "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program". The unpublished rule is available for public inspection at the Federal Register website (Agency Docket: CMS-5531-IFC and Regulation ID Number (RIN): 0938-AU32).

Prior to the COVID-19 PHE and this interim final rule, regulations at 42 CFR §483.80(a)(2)(ii), already required LTC facilities (i.e., skilled nursing facilities and/or nursing facilities) to have written standards, policies and procedures regarding infection control, to include when and to whom possible incidents of communicable disease or infections should be reported, such as to local/state health authorities. In an effort to support surveillance of COVID-19 cases and increase transparency for residents, their representatives, and families, we have added to the infection control requirements provisions to establish reporting for confirmed or suspected COVID-19 cases at new §483.80(g), as follows:

§ 483.80 Infection control.

- (g) COVID-19 Reporting. The facility must—
 - (1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to--
 - (i) Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;
 - (ii) Total deaths and COVID-19 deaths among residents and staff;
 - (iii) Personal protective equipment and hand hygiene supplies in the facility;
 - (iv) Ventilator capacity and supplies in the facility;
 - (v) Resident beds and census;
 - (vi) Access to COVID-19 testing while the resident is in the facility;
 - (vii) Staffing shortages; and
 - (viii) Other information specified by the Secretary.
 - (2) Provide the information specified in paragraph (g)(1) of this section at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.
 - (3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of

respiratory symptoms occurring within 72 hours of each other. This information must—

- (i) Not include personally identifiable information;
- (ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and
- (iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

We understand that state and local health departments may currently require nursing homes to report certain COVID-19 related information to them. A key difference between the state/local reporting and this new national reporting requirement is that reporting to state/local health departments allows them to understand the status of their local environment and intervene (e.g., direct staffing and supplies), whereas this national requirement provides standardized information to assist with national surveillance on the status of COVID-19 in all nursing homes. State and local health departments are also able to submit the required data on behalf of a nursing homes, although this does not relieve facilities of their accountability to report in accordance with the regulation.

Reporting COVID-19 Information to CDC's NHSN

The NHSN <u>Long-Term Care Facility COVID-19 Module</u> is available. Facilities should immediately gain access to the NHSN system and visit the home page for important information, including how to register: https://www.cdc.gov/nhsn/. The following provides an overview of the registration process:

Step 1 – Prepare your computer to interact with NHSN

You may need to change your email and internet security settings to receive communications from NHSN during the enrollment process

Step 2A – Register Facility with NHSN

The person who will serve as the NHSN Facility Administrator must access and read the NHSN Facility/Group Administrator Rules of Behavior from https://nhsn.cdc.gov/RegistrationForm/index

Step 2B – Register with SAMS (Security Access Management System)

After CDC receives your completed registration, you will receive an *Invitation to Register with SAMS* via email

Step 3 – Complete NHSN Enrollment

On the SAMS homepage, click the link to the NHSN labeled **NHSN Enrollment** and Complete Facility Contact Information

Step 4 – Electronically Accept the NHSN Agreement to Participate and Consent

After successfully completing enrollment, the NHSN Facility Administrator and Component Primary Contact (may be the same person) will receive an NHSN email with instructions on how to electronically accept the *NHSN Agreement to Participate and Consent*.

Please note: It is critical for facilities to ensure their CMS Certification Number (CCN) is entered correctly into the NHSN system, so CMS can confirm the facility has met the reporting requirement.

For NHSN questions, please email: <a href="https://www.nhsn.gov.nu/nhsn.gov.nu

Facilities must submit their first set of data by 11:59 p.m. Sunday, May 17, 2020. To be compliant with the new requirement, facilities must submit the data through the NHSN reporting system at least once every seven days. Facilities may choose to submit multiple times a week. CMS is not prescribing which day of the week the data must be submitted, although reporting should remain consistent with data being submitted on the same day(s) each week. The collection period should also remain consistent (e.g., Monday through Sunday). Each Monday, CMS will review the data submitted to assess if each facility submitted data at least once in the previous seven days. The data pulled each Monday will also be used to update the data that is publicly reported.

Updates to the COVID-19 Focused Survey for Nursing Homes

CMS has updated the "COVID-19 Focused Survey for Nursing Homes," "Entrance Conference Worksheet," "COVID-19 Focused Survey Protocol," and "Summary of the COVID-19 Focused Survey for Nursing Homes" to include an updated assessment of the new requirements for facilities to report to the NHSN and to residents, their representatives, and their families. These updated forms are posted to the Survey Resources folder in the COVID-19 Focused Survey subfolder on the CMS Nursing Homes website. Surveyors should begin using these revised documents immediately, and facilities should also begin using the revised "COVID-19 Focused Survey for Nursing Homes" to perform their self-assessment. The documents include the following new deficiency tags for citing noncompliance with the new requirements:

F884: COVID-19 Reporting to CDC as required at §483.80(g)(1)-(2)

Review for F884 will be conducted offsite by CMS Federal surveyors (state surveyors should not cite this F-tag). Following an initial reporting grace period granted to facilities, CMS will receive the CDC NHSN COVID-19 reported data and review for timely and complete reporting of all data elements. Facilities identified as not reporting will receive a deficiency citation at F884 on the CMS-2567 with a scope and severity level at an F (no actual harm with a potential for more than minimal harm that is not an Immediate Jeopardy [IJ] and that is widespread; this is a systemic failure with the potential to affect a large portion or all of the residents or employees), and be subject to an enforcement remedy imposed as described below.

F885: COVID-19 Reporting to Residents, their Representatives, and Families as required at §483.80(g)(3)(i)-(iii)

Review for F885 is included in the "COVID-19 Focused Survey Protocol" and will occur onsite by State and/or Federal surveyors. If the survey finds noncompliance with this requirement, a deficiency citation at this tag will be recorded on the CMS-2567 and enforcement actions will follow the memo QSO-20-20-All. We note that there are a variety of ways that facilities can meet this requirement, such as informing families and representatives through email listservs, website postings, paper notification, and/or recorded telephone messages. We do not expect facilities to make individual telephone calls to each resident's family or responsible party to inform them that a resident in the facility has laboratory-confirmed COVID-19. However, we expect facilities to take reasonable efforts to make it easy for residents, their representatives, and families to obtain the information facilities are required to provide.

In addition, when the State Survey Agency is planning to conduct these surveys, the COVID-19 Focused Survey should be coded in the Automated Survey Process Environment (ASPEN) under "Survey Type" as U=COVID-19. If the survey is taking place with an IJ complaint investigation, the survey should be coded in ASPEN under "Survey Type" as A=complaint and U=COVID-19. This will help ensure consistent, accurate reporting.

Enforcement for F884

A determination that a facility failed to comply with the requirement to report COVID-19 related information to the CDC pursuant to §483.80(g)(1)-(2) (tag F884) will result in an enforcement action. These regulations require a minimum of weekly reporting, and noncompliance with this requirement will receive a deficiency citation and result in a civil money penalty (CMP) imposition. CMS will provide facilities with an initial two-week grace period to begin reporting cases in the NHSN system (which ends at 11:59 p.m. on May 24, 2020). Facilities that fail to begin reporting after the third week (by 11:59 p.m. on May 31st) will receive a warning letter reminding them to begin reporting the required information to CDC. For facilities that have not started reporting in the NHSN system by 11:59 p.m. on June 7th, ending the fourth week of reporting, CMS will impose a per day (PD) CMP of \$1,000 for one day for the failure to report that week. For each subsequent week that the facility fails to submit the required report, the noncompliance will result in an additional oneday PD CMP imposed at an amount increased by \$500. For example, if a facility fails to report in week four (following the two week grace period and receipt of the warning letter), it will be imposed a \$1,000 one-day PD CMP for that week. If it fails to report again in week five, the noncompliance will lead to the imposition of another one-day PD CMP in the amount of \$1,500 for that failure to report (for a CMP total of \$2,500). In this example, if the facility complies with the reporting requirements and submits the required report in week six, but then subsequently fails to report as required in week seven, a one-day PD CMP amount of \$2,000 will be imposed (which is \$500 more than the last imposed PD CMP amount) for a total of \$4,500 imposed CMPs.

For enforcement-related questions, please email: <u>DNH_Enforcement@cms.hhs.gov</u>

Posting Facility-Level COVID-19 Data

Reporting COVID-19 data supports CMS's responsibility to protect and ensure the health and safety of residents and is necessary to ensure the appropriate tracking, response, and mitigation of the spread and impact of COVID-19 on our most vulnerable citizens, personnel who care for them, and the general public. The information provided may be used to inform residents, families, and communities of the status of COVID-19 infections in their area. We believe that this action strengthens CMS's response to the COVID-19 pandemic, and reaffirms our commitment to transparency and protecting the health and safety of nursing home residents. CMS anticipates publicly posting CDC's NHSN data (including facility names, number of COVID-19 suspected and confirmed cases, deaths, and other data as determined appropriate) weekly on https://data.cms.gov/ by the end of May.

Contact: For questions or concerns regarding this memo, please contact DNH_TriageTeam@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Branch training coordinators immediately.

/_S/ David R. Wright

Attachments:

COVID-19 Focused Survey for Nursing Homes Long-term Care Facility Notification Frequently Asked Questions

cc: Survey & Operations Group (SOG) Management