



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

Ref: QSO-20-29-NH

DATE: May 6, 2020

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes

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 The unpublished rule is available for public inspection at [the Federal Register website](#) (Agency Docket: CMS-5531-IFC and Regulation ID Number (RIN): 0938-AU32).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 [Long-Term Care Facility COVID-19 Module](#) 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: NHSN@cdc.gov and add “LTCF” in the subject header.

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 one-day 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: DNH_Enforcement@cms.hhs.gov

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

COVID-19 Focused Survey for Nursing Homes

Infection Control

This survey tool must be used to investigate compliance at F880, **F884 (CMS Federal surveyors only)**, F885, and E0024. Surveyors must determine whether the facility is implementing proper infection prevention and control practices to prevent the development and transmission of COVID-19 and other communicable diseases and infections. Entry and screening procedures as well as resident care guidance has varied over the progression of COVID-19 transmission in facilities. Facilities are expected to be in compliance with CMS requirements and surveyors will use guidance that is in effect at the time of the survey. Refer to QSO memos released at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions>.

This survey tool provides a focused review of the critical elements associated with the transmission of COVID-19, will help surveyors to prioritize survey activities while onsite, and identify those survey activities which can be accomplished offsite. These efficiencies will decrease the potential for transmission of COVID-19, as well as lessen disruptions to the facility and minimize exposure of the surveyor. Surveyors should be mindful to ensure their activities do not interfere with the active treatment or prevention of transmission of COVID-19.

If citing for noncompliance related to COVID-19, the surveyor(s) must include the following language at the beginning of the Deficient Practice Statement or other place determined appropriate on the Form CMS-2567: “Based on [observations/interviews/record review], the facility failed to [properly prevent and/or contain – or other appropriate statement] **COVID-19.**”

If surveyors see concerns related to compliance with other requirements, they should investigate them in accordance with the existing guidance in Appendix PP of the State Operations Manual and related survey instructions. Surveyors may also need to consider investigating concerns related to Emergency Preparedness in accordance with the guidance in Appendix Z of the State Operations Manual (e.g., for emergency staffing).

For the purpose of this survey tool, “staff” includes employees, consultants, contractors, volunteers, and others who provide care and services to residents on behalf of the facility. The Infection Prevention and Control Program (IPCP) must be facility-wide and include all departments and contracted services.

Critical Element #8 is only for consideration by CMS Federal Survey staff. Information to determine the facility’s compliance at F884 is only reported to each of the 10 CMS locations.

Surveyor(s) reviews for:

- The overall effectiveness of the Infection Prevention and Control Program (IPCP) including IPCP policies and procedures;
- Standard and Transmission-Based Precautions;
- Quality of resident care practices, including those with COVID-19 (laboratory-positive case), if applicable;
- The surveillance plan;

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- Visitor entry and facility screening practices;
- Education, monitoring, and screening practices of staff;
- Facility policies and procedures to address staffing issues during emergencies, such as transmission of COVID-19; and
- How the facility informs residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility.

1. Standard and Transmission-Based Precautions (TBPs)

CMS is aware that there is a scarcity of some supplies in certain areas of the country. State and Federal surveyors should not cite facilities for not having certain supplies (e.g., PPE such as gowns, N95 respirators, surgical masks) if they are having difficulty obtaining these supplies for reasons outside of their control. However, we do expect facilities to take actions to mitigate any resource shortages and show they are taking all appropriate steps to obtain the necessary supplies as soon as possible. For example, if there is a shortage of PPE (e.g., due to supplier(s) shortage which may be a regional or national issue), the facility should contact their health department or healthcare coalition for assistance (<https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx>), follow national and/or local guidelines for optimizing their current supply or identify the next best option to care for residents. Among other practices, optimizing their current supply may mean prioritizing use of gowns based on risk of exposure to infectious organisms, blood or body fluids, splashes or sprays, high contact procedures, or aerosol generating procedures (AGPs), as well as possibly extending use of PPE (follow national and/or local guidelines). Current CDC guidance for healthcare professionals is located at: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html> and healthcare facilities is located at: <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html>. Guidance on strategies for optimizing PPE supply is located at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html>. If a surveyor believes a facility should be cited for not having or providing the necessary supplies, the State Agency should contact the CMS Regional Location.

General Standard Precautions:

Are staff performing the following appropriately:

- Respiratory hygiene/cough etiquette,
- Environmental cleaning and disinfection, and
- Reprocessing of reusable resident medical equipment (e.g., cleaning and disinfection of glucometers per device and disinfectant manufacturer's instructions for use)?

Hand Hygiene:

Are staff performing hand hygiene when indicated?

If alcohol-based hand rub (ABHR) is available, is it readily accessible and preferentially used by staff for hand hygiene?

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- If there are shortages of ABHR, are staff performing hand hygiene using soap and water instead?
- Are staff washing hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids)?
- Do staff perform hand hygiene (even if gloves are used) in the following situations:
 - Before and after contact with the resident;
 - After contact with blood, body fluids, or visibly contaminated surfaces;
 - After contact with objects and surfaces in the resident's environment;
 - After removing personal protective equipment (e.g., gloves, gown, facemask); and
 - Before performing a procedure such as an aseptic task (e.g., insertion of an invasive device such as a urinary catheter, manipulation of a central venous catheter, and/or dressing care)?
- When being assisted by staff, is resident hand hygiene performed after toileting and before meals?
- Interview appropriate staff to determine if hand hygiene supplies (e.g., ABHR, soap, paper towels) are readily available and who they contact for replacement supplies.

Personal Protective Equipment (PPE):

- Determine if staff appropriately use PPE including, but not limited to, the following:
 - Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;
 - Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;
 - Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care; and
 - An isolation gown is worn for direct resident contact if the resident has uncontained secretions or excretions.
- Is PPE appropriately removed and discarded after resident care, prior to leaving room (except in the case of extended use of PPE per national/local recommendations), followed by hand hygiene?
- If PPE use is extended/reused, is it done according to national and/or local guidelines? If it is reused, is it cleaned/decontaminated/maintained after and/or between uses?
- Interview appropriate staff to determine if PPE is available, accessible and used by staff.
 - Are there sufficient PPE supplies available to follow infection prevention and control guidelines? In the event of PPE shortages, what procedures is the facility taking to address this issue?
 - Do staff know how to obtain PPE supplies before providing care?
 - Do they know who to contact for replacement supplies?

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Transmission-Based Precautions (Note: PPE use is based on availability and latest CDC guidance. See note on Pages 1-2):

Determine if appropriate Transmission-Based Precautions are implemented:

- For a resident on Contact Precautions: staff don gloves and isolation gown before contact with the resident and/or his/her environment;
- For a resident on Droplet Precautions: staff don a facemask within six feet of a resident;
- For a resident on Airborne Precautions: staff don an N95 or higher level respirator prior to room entry of a resident;
- For a resident with an undiagnosed respiratory infection: staff follow Standard, Contact, and Droplet Precautions (i.e., facemask, gloves, isolation gown) with eye protection when caring for a resident unless the suspected diagnosis requires Airborne Precautions (e.g., tuberculosis);
- For a resident with known or suspected COVID-19: staff wear gloves, isolation gown, eye protection and an N95 or higher-level respirator if available. A facemask is an acceptable alternative if a respirator is not available. Additionally, if there are COVID-19 cases in the facility or sustained community transmission, staff implement universal use of facemasks while in the facility (based on availability). When COVID-19 is identified in the facility, staff wear all recommended PPE (i.e., gloves, gown, eye protection and respirator or facemask) for the care of all residents on the unit (or facility-wide based on the location of affected residents), regardless of symptoms (based on availability).
 - Some procedures performed on residents with known or suspected COVID-19 could generate infectious aerosols (i.e., aerosol-generating procedures (AGPs)). In particular, procedures that are likely to induce coughing (e.g., sputum induction, open suctioning of airways) should be performed cautiously. If performed, the following should occur:
 - Staff in the room should wear an N95 or higher-level respirator, eye protection, gloves, and an isolation gown.
 - The number of staff present during the procedure should be limited to only those essential for resident care and procedure support.
 - AGPs should ideally take place in an airborne infection isolation room (AIIR). If an AIIR is not available and the procedure is medically necessary, then it should take place in a private room with the door closed.
 - Clean and disinfect the room surfaces promptly and with appropriate disinfectant. Use disinfectants on List N of the EPA website for EPA-registered disinfectants that have qualified under EPA's emerging viral pathogens program for use against SARS-COV-2 or other national recommendations;
- Dedicated or disposable noncritical resident-care equipment (e.g., blood pressure cuffs, blood glucose monitor equipment) is used, or if not available, then equipment is cleaned and disinfected according to manufacturers' instructions using an EPA-registered disinfectant for healthcare setting prior to use on another resident;
- Objects and environmental surfaces that are touched frequently and in close proximity to the resident (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) are cleaned and disinfected with an EPA-registered disinfectant for healthcare setting (effective against the organism identified if known) at least daily and when visibly soiled; and
- Is signage on the use of specific PPE (for staff) posted in appropriate locations in the facility (e.g., outside of a resident's room, wing, or facility-wide)?

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- Interview appropriate staff to determine if they are aware of processes/protocols for Transmission-Based Precautions and how staff is monitored for compliance.
- If concerns are identified, expand the sample to include more residents on Transmission-Based Precautions.

1. Did staff implement appropriate Standard (e.g., hand hygiene, appropriate use of PPE, environmental cleaning and disinfection, and reprocessing of reusable resident medical equipment) and Transmission-Based Precautions (if applicable)? Yes No F880

2. Resident Care

- If there is sustained community transmission or case(s) of COVID-19 in the facility, is the facility restricting residents (to the extent possible) to their rooms except for medically necessary purposes? If there is a case in the facility, and residents have to leave their room, are they wearing a facemask, performing hand hygiene, limiting their movement in the facility, and performing social distancing (efforts are made to keep them at least 6 feet away from others). If PPE shortage is an issue, facemasks should be limited to residents diagnosed with or having signs/symptoms of respiratory illness or COVID-19.
- Has the facility cancelled group outings, group activities, and communal dining?
- Has the facility isolated residents with known or suspected COVID-19 in a private room (if available), or taken other actions based on national (e.g., CDC), state, or local public health authority recommendations?
- For the resident who develops severe symptoms of illness and requires transfer to a hospital for a higher level of care, did the facility alert emergency medical services and the receiving facility of the resident's diagnosis (suspected or confirmed COVID-19) and precautions to be taken by transferring and receiving staff as well as place a facemask on the resident during transfer (as supply allows)?
- For residents who need to leave the facility for care (e.g. dialysis, etc.), did the facility notify the transportation and receiving health care team of the resident's suspected or confirmed COVID-19 status?
- Does the facility have residents who must leave the facility regularly for medically necessary purposes (e.g., residents receiving hemodialysis and chemotherapy) wear a facemask (if available) whenever they leave their room, including for procedures outside of the facility?

2. Did staff provide appropriate resident care? Yes No F880

3. IPCP Standards, Policies and Procedures

- Did the facility establish a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19?

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- Does the facility's policies or procedures include when to notify local/state public health officials if there are clusters of respiratory illness or cases of COVID-19 that are identified or suspected?
- Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

3. Does the facility have a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19? Yes No F880

4. Infection Surveillance

- How many residents and staff in the facility have fever, respiratory signs/symptoms, or other signs/symptoms related to COVID-19?
- How many residents and staff have been diagnosed with COVID-19 and when was the first case confirmed?
- How many residents and staff have been tested for COVID-19? What is the protocol for determining when residents and staff should be tested?
- Has the facility established/implemented a surveillance plan, based on a facility assessment, for identifying (i.e., screening), tracking, monitoring and/or reporting of fever (at a minimum, temperature is taken per shift), respiratory illness, and/or other signs/symptoms of COVID-19 and immediately isolate anyone who is symptomatic?
- Does the plan include early detection, management of a potentially infectious, symptomatic resident that may require laboratory testing and/or Transmission-Based Precautions/PPE (the plan may include tracking this information in an infectious disease log)?
- Does the facility have a process for communicating the diagnosis, treatment, and laboratory test results when transferring a resident to an acute care hospital or other healthcare provider; and obtaining pertinent notes such as discharge summary, lab results, current diagnoses, and infection or multidrug-resistant organism colonization status when residents are transferred back from acute care hospitals?
- Can appropriate staff (e.g., nursing and unit managers) identify/describe the communication protocol with local/state public health officials?
- Interview appropriate staff to determine if infection control concerns are identified, reported, and acted upon.

4. Did the facility provide appropriate infection surveillance? Yes No F880

5. Visitor Entry

- Review for compliance of:
- Screening processes and criteria (i.e., screening questions and assessment of illness);
 - Restriction criteria; and

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- Signage posted at facility entrances for screening and restrictions as well as a communication plan to alert visitors of new procedures/restrictions.
- For those permitted entry, are they instructed to frequently perform hand hygiene; limit their interactions with others in the facility and surfaces touched; restrict their visit to the resident's room or other location designated by the facility; and offered PPE (e.g., facemask) as supply allows? What is the facility's process for communicating this information?
- For those permitted entry, are they advised to monitor for signs and symptoms of COVID-19 and appropriate actions to take if signs and/or symptoms occur?

5. Did the facility perform appropriate screening, restriction, and education of visitors? Yes No F880

6. Education, Monitoring, and Screening of Staff

- Is there evidence the facility has provided education to staff on COVID-19 (e.g., symptoms, how it is transmitted, screening criteria, work exclusions)?
- How does the facility convey updates on COVID-19 to all staff?
- Is the facility screening all staff at the beginning of their shift for fever and signs/symptoms of illness? Is the facility actively taking their temperature and documenting absence of illness (or signs/symptoms of COVID-19 as more information becomes available)?
- If staff develop symptoms at work (as stated above), does the facility:
- Place them in a facemask and have them return home;
 - Inform the facility's infection preventionist and include information on individuals, equipment, and locations the person came in contact with; and
 - Follow current guidance about returning to work (e.g., local health department, CDC: <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/hcp-return-work.html>).

6. Did the facility provide appropriate education, monitoring, and screening of staff? Yes No F880

7. Reporting to Residents, Representatives, and Families

Identify the mechanism(s) the facility is using to inform residents, their representatives, and families (e.g., newsletter, email, website, recorded voice message)

- Did the facility inform all residents, their representatives, and families by 5 PM the next calendar day following the occurrence of a single confirmed COVID-19 infection or of three or more residents or staff with new onset of respiratory symptoms that occurred within 72 hours of each other?

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- Did the information include mitigating actions taken by the facility to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered (e.g., restrictions to visitation or group activities)?
- Did the information include personally identifiable information?
- Is the facility providing cumulative updates to residents, their representatives, and families at least weekly or by 5 PM the next calendar day following the subsequent occurrence of either: each time a confirmed COVID-19 infection is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other?
- Interview a resident and a resident representative or family member to determine whether they are receiving timely notifications.

7. Did the facility inform residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility along with mitigating actions in a timely manner? Yes No F885

8. Reporting to the Centers for Disease Control and Prevention (CDC) – Performed Offsite by CMS. For consideration by CMS Federal Surveyors only.

- Review CDC data files provided to CMS to determine if the facility is reporting at least once a week.
- Review data files to determine if all data elements required in the National Healthcare Safety Network (NHSN) COVID-19 Module are completed.

8. Did the facility report at least once a week to CDC on all of the data elements required in the NHSN COVID-19 Module?

Yes No F884

9. Emergency Preparedness – Staffing in Emergencies

- Policy development: Does the facility have a policy and procedure for ensuring staffing to meet the needs of the residents when needed during an emergency, such as COVID-19 outbreak?
- Policy implementation: In an emergency, did the facility implement its planned strategy for ensuring staffing to meet the needs of the residents? (N/A if an emergency staff was not needed).

9. Did the facility develop and implement policies and procedures for staffing strategies during an emergency?

Yes No E0024 N/A

COVID-19 Focused Survey for Nursing Homes

Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive Paperwork Reduction Act (PRA) (44 USC 3501 et seq.) requirements with respect to voluntary collection of information during a public health emergency (PHE), as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). Under this new authority, the HHS Secretary may waive PRA requirements for the voluntary collection of information if the Secretary determines that: (1) a PHE exists according to section 319(a) of the PHS Act or determines that a disease or disorder, including a novel and emerging public health threat, is a SLPHE under section 319(f) of the PHS Act; and (2) the PHE/SLPHE, including the specific preparation for and response to it, necessitates a waiver of the PRA requirements. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been designated as the office that will coordinate the process for the Secretary to approve or reject each request.

The information collection requirements contained in this information collection request have been submitted and approved under a PRA Waiver granted by the Secretary of Health and Human Services. The waiver can be viewed at <https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers>.

**Long-term Care (LTC) Facility Requirements for Notification of Confirmed and Suspected Coronavirus Disease 2019 (COVID-19) Cases Among Residents and Staff:
Frequently Asked Questions (FAQs)**

May 6, 2020

The purpose of this FAQ is to provide additional information on the updated reporting requirements for LTC facilities at 42 CFR §483.80(g), which will be published on May 8, 2020, in an interim final rule with comment period. The unpublished rule is available for public inspection at [the Federal Register website](#). The new reporting requirements specify that facilities must report COVID-19 data to the Centers for Disease Control and Prevention (CDC), and to all residents, their representatives, and families.

Note: The terms “nursing home” and “long-term care facility” are used interchangeably in this document, and both refer to a facility that is certified to provide Medicare skilled nursing facility (SNF) services, and/or Medicaid nursing facility (NF) services.

Reporting to CDC’s National Healthcare Safety Network (NHSN)

1. Q: What actions are the Centers for Medicare & Medicaid Services (CMS) taking by revising the Requirements for Participation for LTC facilities?

A: CMS is requiring facilities to report COVID-19 facility data on residents and staff to CDC and to residents, their representatives, and families of residents in facilities. 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 these COVID-19 reporting requirements and created two new deficiency tags (F884 and F885). Facilities must submit data through [CDC NHSN Long-Term Care Facility COVID-19 Module](#) at least once a week. CMS will begin posting aggregated data from CDC NHSN to <https://data.cms.gov/> by the end of May for viewing by LTC facilities, stakeholders, and the general public.

2. Q: How will CMS and CDC use this information?

A: CDC will use information collected through the new NHSN Long-Term Care Facility COVID-19 Module to strengthen COVID-19 surveillance locally and nationally. Nursing home reporting to CDC is a critical component of national COVID-19 surveillance efforts and is consistent with White House guidelines, [Opening Up America Again](#). CMS will use the information to ensure nursing homes are following all requirements for participation, specifically those focused on infection control. CMS may also use the information to determine survey prioritization.

Facility-level data collected through NHSN as part of the [Long-Term Care Facility COVID-19 Module](#) will also be available to a broader set of federal, state, and local agencies. Specifically, COVID-19 data at the state, county, territory, and facility level submitted to

NHSN will continue to be used for public health emergency response activities by CDC's emergency COVID-19 response, by the U.S. Department of Health and Human Services' (HHS') COVID-19 tracking system maintained in the Office of the Assistant Secretary of Preparedness and Response (ASPR) as part of the National Response Coordination Center at the Federal Emergency Management Agency (FEMA), and by the White House Coronavirus Task Force.¹

3. Q: If states are already collecting COVID-19 information from nursing homes, why is CMS requiring it to be reported to CDC?

A: The new reporting tool complements existing, state level reporting efforts. Due to variation in state and local reporting requirements for COVID-19, NHSN's Long-Term Care Facility Module aims to provide a standardized, national lens on the experience of long-term care facilities to support and inform the public health response at the local, state, and federal levels.

The NHSN Module is not intended as a replacement for state and local public health reporting requirements, and nursing homes are required to continue to report COVID-19 data to state and local health departments in accordance with state and local requirements via existing mechanisms. In some public health jurisdictions, the data that nursing homes report to the new module may supplement the data that they already report to state and local public health authorities. NHSN uses existing functionality (NHSN's Group Function) to make COVID-19 data immediately accessible to state and local health departments for surveillance and public health response decisions. State and local health departments are also able to submit the required data on behalf of nursing homes, although this does not relieve facilities of their accountability to report in accordance with the regulation.

4. Q. Will CDC offer technical assistance/user support to facilities to help them begin reporting data?

A: Yes, CDC will offer users training and technical support through a variety of mechanisms, including the following:

- Detailed instructions and copies of the reporting forms, which will be posted on the NHSN Long-Term Care Facility COVID-19 Module [webpage](#)
- Web-based trainings, which will be recorded and similarly posted to the NHSN Long-Term Care Facility [webpage](#)
- Live office hours, which will offer participants an opportunity to ask detailed questions and receive answers from CDC subject matter experts
- E-mail updates on new functions or resources available through NHSN
- Response to questions submitted to: NHSN@cdc.gov

¹ Members of the White House Coronavirus Task Force are listed here:

<https://www.whitehouse.gov/briefings-statements/vice-president-pence-secretary-azar-add-key-administration-officials-coronavirus-task-force-2/>

<https://www.whitehouse.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/>

5. Q: Can state health departments report COVID-19 data to NHSN on a nursing home's behalf?

A: Yes. Each nursing home must first enroll in NHSN to submit its data. Once enrolled, state and local health departments may submit data on behalf of a nursing home. Additionally, data can be batched and submitted as a single file for multiple facilities. We note this does not relieve facilities of their accountability to report in accordance with the regulation. CDC and CMS will work with state health departments and other partners to enable batch data reporting by state health departments or other entities (such as state hospital associations, corporate headquarters and IT vendors). CDC and CMS will work with state health departments and other partners to communicate and help them utilize this option.

6. Q: How will nursing homes know their data was received?

A: Nursing homes will be able to view their data in the NHSN application upon data submission. NHSN's analysis and reporting features allows nursing homes to quickly verify that their data have been received.

7. Q: Will CMS cite facilities for noncompliance at F884 and penalize any nursing home with a case of COVID-19 reported to CDC's NHSN?

A: The presence of COVID-19 in a nursing home does not automatically mean that noncompliance exists. CMS will not use the data to penalize nursing homes for the presence of COVID-19. Until further notice, surveys will continue to be conducted in accordance with CMS memorandum [QSO-20-20-All](#), which includes surveying for Immediate Jeopardy allegations and Focused Infection Control surveys. CMS has updated the COVID-19 Focused Survey for Nursing Homes with processes related to the new reporting requirements. Surveyors will only cite noncompliance with federal requirements for infection control and prevention based on their investigations, and not based on the COVID-19 information reported through the NHSN system.

We note, however, that facilities will be cited and subject to enforcement action for not submitting complete data through the NHSN system in accordance with the new reporting requirements.

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) civil money penalty (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 one-day 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 PD CMPs). 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.

8. Q: What if a facility under-reports COVID-19 data to CDC's NHSN?

A: CMS expects facilities to submit complete and accurate information through the NHSN system. We understand identifying cases of COVID-19 in a nursing home can be challenging. However, accurate data is critical to directing public health action and ensuring critical resources and assistance are available to facilities that need them. If, upon further investigation, CMS identifies that a facility did not submit complete and accurate information, the facility would not be in compliance with the new reporting requirements and would be subject to enforcement actions.

9. Q: How long will reporting to CDC's NHSN system and to residents, resident representatives, and families continue to be required?

A: These requirements go into effect with the publication of the interim final rule. CMS will inform the public and all stakeholders of any changes in the reporting requirements. Until any changes are announced, these requirements remain in effect.

10. Q: Are facilities required to report data that predates the effective date of the interim final rule?

A: No, there is no requirement in the rule to collect older data. The NHSN system has capability for retrospective reporting from January 2020 onward, consistent with CDC's mission-critical work, but CMS will not take enforcement action if a nursing home is unable to accurately report information from that time. However, we encourage facilities to report older data as it will help with CDC's ongoing surveillance and response efforts to assess burden of COVID-19 in nursing homes, and support a comprehensive national surveillance of the pandemic.

11. Q: Must a facility report deaths of residents which occur in hospitals to the NHSN's LTCF COVID-19 Module?

A: Yes, the LTCF COVID-19 Module does include reporting of deaths in another location. This is clarified in the [COVID-19 module instructions](#) that facilities will use when reporting on resident impact and facility capacity.

Reporting COVID-19 Activity to Residents, Their Representatives, and Families

12. Q: Must the facility notify all residents, representatives, and families, or just those affected?

A: Facilities must notify all residents in the facility, their representatives, and families, not just those who are suspected or confirmed cases of COVID-19. Notification must include data when a confirmed COVID-19 case is identified or when three or more residents or staff have new onset of respiratory symptoms that occur within 72 hours of each other in the facility. Cumulative updates must be provided when other confirmed cases or clusters of three or more residents or staff with respiratory symptoms occur within 72 hours of each other, and at least weekly. 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, 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 make all reasonable efforts to properly inform residents, their representatives, and families of the information facilities are required to provide.

13. Q: What information is required to be reported to residents, their representatives, and families? Will this information include new cases as well as total cases?

A: Cumulative, confirmed COVID-19 cases as well as clusters of three or more residents or staff with respiratory symptoms within 72 hours must be reported. The facility is not required to identify new versus total cases.

14. Q: Can you clarify what symptoms CMS is referring to in the requirement to report if three or more residents or staff have respiratory symptoms within 72 hours of each other?

A: Respiratory symptoms consistent with COVID-19 are shortness of breath, difficulty breathing, new or change in cough, sore throat, or new loss of taste or smell. To a lesser extent, symptoms have included new sputum production, rhinorrhea, or hemoptysis. For more information on updated symptoms, please view CDC's webpages: [Symptoms of Coronavirus and Preparing for COVID-19: Long-term Care Facilities, Nursing Homes](#).

15. Q: Must the facility report any suspected case of COVID-19 of a resident or staff member to residents, their representatives, and families?

A: No. The regulation does not require facilities to report to residents, their representatives, and families every suspected case of COVID-19 in residents and staff of the facility. However, it does require facilities to report suspected cases when three or more occur within 72 hours of each other.

16. Q: For dedicated COVID-19 facilities and those with COVID-19 units, must they inform residents, their representatives, and families each time a new resident with confirmed COVID-19 is admitted or staff member tests positive? Similarly, what is the time frame for notifying residents, their representatives, and families for subsequent COVID-19 activity?

A: Yes. The facility must provide any cumulative updates for residents, their representatives, and families. Updates must occur at least weekly or by 5 PM the next calendar day following the subsequent occurrence of either: a confirmed infection of COVID-19 is identified (including new admissions), or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

17. Q: Who are considered “staff” for purposes of reporting confirmed cases or clusters of respiratory symptoms to residents, their representatives, and families?

A: “Staff” includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents in the facility, including nurse aides that have not yet completed a nurse aide training, competency, and evaluation program (NATCEP) but are providing services to residents.

18. Q: When informing residents, their representatives, and families of suspected and confirmed COVID-19 cases in the facility, does the facility have to specify whether individual cases are residents or staff?

A: No. CMS does not require this.

19. Q: Do facilities need to inform anyone who walks through their doors (e.g., a hospice or other healthcare provider) of the same numbers of suspected and confirmed COVID-19 cases that they are sharing with residents, their representatives, and families?

A: No. Facilities are not required to provide the same COVID-19 information reported to residents, their representatives, and families. However, facilities would share with the visiting healthcare provider, if the resident receiving care is suspected of, or has laboratory-confirmed COVID-19. Any precautions the provider should take while in the facility (e.g., specific personal protective equipment) will be communicated to that provider by the facility as part of their standard practices under the infection prevention and control program requirement.

20. Q: What if a facility has never had a suspected or confirmed COVID-19 case? Is the facility required to inform all residents, their representatives, and families?

A: No. CMS does not require this, however, we encourage facilities to transparently communicate regularly with residents, their representatives, and families about the status of the facility.

21. Q: What if a facility has three or more residents or staff with new onset of respiratory symptoms but not within 72 hours of each other? Does the facility still need to report this to all residents, their representatives, and families?

A: No. CMS does not require this.

22. Q: Does the reporting requirement at 42 CFR §483.80(g)(3)(i)-(iii) (F885) fulfill the requirement at §483.10(g)(14)(i)(B), Notification of Changes (F580)?

A: No. The new reporting requirement at §483.80(g)(3)(i)-(iii) (F885) requires facilities to notify residents, their representatives, and families of cumulative numbers of confirmed COVID-19 cases and clusters of three or more residents or staff with respiratory symptoms within 72 hours of each other. By way of comparison, §483.10(g)(14)(i)(B) requires nursing homes to notify the resident, the resident's physician and as applicable, the resident's representative(s) of an individual resident's change in condition (F580) if he/she is suspected or confirmed to have COVID-19.