CMS Testing and Visitation QSO-20-38 NH & QSO 20-39 NH

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COVID 19 Focused Survey for Nursing Homes

Updated Protocols

Refer to the latest Guidance

- Preparing for COVID-19 in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html
- Responding to Coronavirus (COVID-19) in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-responding.html
- Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance): https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html

Surveyors use the following tools

- COVID-19 Focused Survey Protocol
- COVID-19 Focused Survey *for Nursing Homes*
- *COVID-19 Entrance Conference Worksheet*
- *CMS Memorandum QSO 20-38 NH: Related to Nursing Home Testing of Residents and Staff*

Off Site Activities: additions

Offsite activities that may take place after the team enters the facility unannounced:

o Medical record reviews, *including resident test results*;

o *Staff test results*;

o *County-level positivity rates found at https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg*

Off site additions continued:

- Facility Policy/Procedure Reviews (e.g., Infection Control and Prevention Program, Emergency Preparedness Plan, *residents and staff who refuse testing or are unable to be tested*);

On site Activities: Additional Review for:

-Effectiveness of the IPCP including policy and procedures: review care of a resident under observation, suspected of, or confirmed to have COVID-19 Infections.

-Quality of resident care practices including those under observation, suspected of and confirmed to have COVID-19 infection

-The surveillance and testing process

-Actions taken to prevent transmission, such as co-horting and managing care for resident suspected of having or confirmed to have COVID 19 Action

Onsite Activities: additions

Interviews with relevant staff:

- Surveillance for sign/symptoms *and COVID-19 testing*
- Notifying local health officials *(e.g., surveillance, supply shortages)*
- Discussion and review documentation of the facilities testing.

Entrance Conference Additions

- A copy of an updated facility floor plan, if changes have been made, including observation and COVID-19 units.

Within one hour

- The actual working schedules for all staff, separated by departments, for the survey time period.

- Facility Policies and Procedures:
  - Procedures to address resident and staff who refuse testing or are unable to be tested.

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Entrance Conference Additions

Documentation related to COVID-19 testing, which may include:

-the facility's testing plan,

-logs of county level positivity rates,

-testing schedules,

-list of staff who have confirmed or suspected cases of COVID-19,

- and if there were testing issues, contact with state and local health departments.

Surveyors additional review:

- The infection preventionist role (see F 882)
- The survey team will select a random sample of three residents and if not already sampled, add one additional resident who was confirmed COVID-10 positive or had signs or symptoms consistent with COVID=19 for purposes of determining compliance.
- The survey team will select a random sample of three staff, and if not already sampled, add one addition staff who was confirmed COVID -19 positive or had signs or symptoms consistent with COVID-10 for purpose of determining compliance.

Surveyor Observations, Reviews and Interviews include:

Hand Hygiene

How are residents reminded to perform hand hygiene?

Staff hygiene all staff

PPE

An isolation gown, eye protection (eg goggles or face shield) and an N95 or equivalent or higher-level respirator are worn for direct resident contact if the resident has uncontained secretions or excretions including splashes or sprays.

Are all staff wearing a facemask (e.g. face covering can be used by staff where PPE is not indicated, such as administrative staff who are not a risk of coming in contact with infectious materials)?

Are residents, visitors and other at the facility donning a cloth face covering or facemask while in the facility or while around others outside?

PPE

When COVID-19 is present in the facility, are staff wearing an N95 or equivalent or higher-level respirator, instead of a facemask, for aersol generating procedures?

Are residents visitors and others at the facility donning a cloth face covering or facemask while in the facility or while around other outside?

Survey Protocol

- 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.
- 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 *(effective against the identified organism if known)* prior to use on another resident;
- *Observe staff to determine if they use appropriate infection control precautions when moving between resident rooms, units and other areas of the facility.*

Resident Care

Residents on Transmission-Based Precautions restricted to their rooms except for medically necessary purposes? If these residents have to leave their room, are they wearing a facemask *or cloth face covering*, 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)?

Residents not on Transmission-Based Precautions are outside of their room, are they wearing a cloth face covering or facemask as part of source control? If a cloth face covering or facemask is not tolerated, does the resident cover his/her mouth and nose with tissues and is reminded or assisted to perform hand hygiene? Is at least 6 feet maintained between residents? If not why? And what measures are being used to mitigate?

Resident Care

- The facility *ensuring only COVID-19 negative residents* and those not suspected or under observation for COVID-19 *are participating in group outings (e.g., if in phase 2 or 3 of CMS' QSO-20-30-NH- " Nursing Home Reopening Recommendations for State and Local Officials"), group activities, and communal dining following State and local official guidance if more restrictive?*
- *Is the facility ensuring that residents are maintaining social distancing (e.g., limited number of people in areas and spaced by at least 6 feet), performing hand hygiene, and wearing cloth face coverings?*

Resident Care

- The facility must have a plan (including appropriate placement and PPE use) to manage residents that are new/readmissions under observation, those exposed to COVID-19, and those suspected of COVID-19? Are these actions based on national (e.g., CDC), state, or local public health authority recommendations?
- The facility have a plan to prevent transmission, such as having a dedicated space in the facility for cohorting and managing care for residents with COVID-19? Are these actions based on national (e.g., CDC), state, or local public health authority
- What about transferring staff in and out of the building? Are receiving staff as well as place a facemask or cloth face covering on the resident during transfer (as tolerated)?

Visitors (things surveyors review)

- 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(s) designated by the facility*; maintain at least six feet from others in the facility;*
  - and *wear a cloth face covering or facemask during the duration of their visit*?
  - What is the facility's process for communicating this information?

Education, Monitoring, Screening of Staff

- Are non-essential staff permitted into the facility based on state or federal guidance (e.g., reopening recommendations include
- Phase 1: nonessential staff limited;
- Phase 2: limited numbers of non-essential staff allowed;
- Phase 3: all non-essential staff allowed)?

During interview with facility administration and Infection Preventionist(s), determine the following:

Does the facility designate one or more individual(s) as the infection preventionist(s) who are responsible for the facility's IPCP?

Does the Infection Preventionist(s) work at least part-time at the facility?

Does the Infection Preventionist(s) completed specialized training in infection prevention and control?

Infection Preventionist: IC Survey

Staff and Resident Testing IC Survey

Review the facility's testing documentation (e.g., logs of county level positivity rate, testing schedules, staff and resident records, other documentation).

- If possible, observe how the facility conducts testing, including the use of PPE and specimen collection. If such observation is not possible, interview an individual responsible for testing and inquire how testing is conducted (e.g., "what are the steps taken to conduct each test?").
- Did the facility conduct testing of staff based on the county level positivity rate according to the recommended frequency?
- Based on observation or interview, did the facility conduct testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests?

Continued

- Did the facility's documentation demonstrate the facility conducted testing of residents or staff with signs of symptoms of COVID-19 in a manner that is consistent with current standards of practice for conducting COVID-19 tests?

Continued

- Did the facility take actions to prevent the transmission of COVID-19 upon the identification of an individual with symptoms consistent with or who tests positive for COVID-19?
- Did the facility have procedures for addressing residents and staff that refuse testing or are unable to be tested?
- if there was an issue related to testing supplies or processing tests, did the facility contact the state and local health departments for assistance?

***Note: If no to any of the question above, consider citing F886.

CMS QSO 20-38 Testing

- CMS's recommendation below to test with authorized nucleic acid or antigen detection assays is an important addition to other infection prevention and control (IPC) recommendations aimed at preventing COVID-19 from entering nursing homes, detecting cases quickly, and stopping transmission. Swift identification of confirmed COVID-19 cases allows the facility to take immediate action to remove exposure risks to nursing home residents and staff. CMS has added
- 42 CFR § 483.80(h) which requires that the facility test all residents and staff for COVID-19. Guidance related to the requirements is located below. Noncompliance related to this new requirement will be cited at new tag F886.
- Published in the federal register September 2

F 886: Infection control

- § 483.80(h) *COVID-19 Testing*. The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

F 886 continued

(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

(3) For each instance of testing:

(i) Document that testing was completed and the results of each staff test; and

(ii) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

(1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:

(i) Testing frequency;

(ii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;

(iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID -19 or with known or suspected exposure to COVID-19

(iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;

(v) The response time for test results; and

(vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

F 886 continued…..

2) Conduct Testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests:

3) For each instance of testing

(1) Document that testing was completed and the results of each staff test and

(2) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

continued…..

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.

(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

Guidance for 886

Testing of Nursing Home Staff and Residents

- To enhance efforts to keep COVID-19 from entering and spreading through nursing homes, facilities are required to test residents and staff based on parameters and a frequency set forth by the HHS Secretary.
- Facilities can meet the testing requirements through the use of rapid point-of-care (POC) diagnostic testing devices or through an arrangement with an offsite laboratory. POC Testing is diagnostic testing that is performed at or near the site of resident care. For a facility to conduct these tests with their own staff and equipment (including POC devices provided by the Department of Health and Human Services), the facility must have a CLIA Certificate of Waiver. Information on obtaining a CLIA Certificate of Waiver can be found here.

Testing Requirements

- Facilities without the ability to conduct COVID-19 POC testing should have arrangements with a laboratory to conduct tests to meet these requirements. Laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected to rapidly inform infection prevention initiatives to prevent and limit transmission.

Definitions

- **"Facility staff"** includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions. **For the purpose of testing "individuals providing services under arrangement and volunteers," facilities should prioritize those individuals who are regularly in the facility (e.g., weekly) and have contact with residents or staff**. We note that the facility may have a provision under its arrangement with a vendor or volunteer that requires them to be tested from another source (e.g., their employer or on their own). However, the facility is still required to obtain documentation that the required testing was completed during the timeframe that corresponds to the facility's testing frequency, as described in Table 2 below.

Facility Staff cont…..

- Regardless of the frequency of testing being performed or the facility's COVID-19 status, the facility should continue to screen all staff (each shift), each resident (daily), and all persons entering the facility, such as vendors, volunteers, and visitors, for signs and symptoms of COVID-19.
- When prioritizing individuals to be tested, facilities should prioritize individuals with signs and symptoms of COVID-19 first, then perform testing triggered by an outbreak (as specified below).

Table 1: Testing Summary

Testing Trigger	Staff	Residents
Symptomatic individual identified	Staff with signs and symptoms must be tested	Residents with signs and symptoms must be tested
Outbreak (any new case arises in facility)	Test all staff that previously tested negative until no new cases are identified*	Test all residents that previously tested negative until no new cases are identified*
Routine testing	According to Table 2 below	Not recommended, unless the resident leaves the facility routinely

notes

*For outbreak testing, all staff and residents should be tested, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. For more information, please review the section below titled, "Testing of Staff and Residents in Response to an Outbreak."

Testing of Staff and Residents with COVID-19 Symptoms or Signs

- Staff with symptoms or signs of COVID-19 must be tested and are expected to be restricted from the facility pending the results of COVID-19 testing. If COVID-19 is confirmed, staff should follow Centers for Disease Control and Prevention (CDC) guidelines "Criteria for Return to Work for Healthcare Personnel with SARS-CoV2 Infection." Staff who do not test positive for COVID-19 but have symptoms should follow facility policies to determine when they can return to work.
- Residents who have signs or symptoms of COVID-19 must be tested. While test results are pending, residents with signs or symptoms should be placed on transmission-based precautions (TBP) in accordance with CDC guidance. Once test results are obtained, the facility must take the appropriate actions based on the results.
- Note: Concerns related to initiating and/or maintaining TBP should be investigated under F880, Infection Control.

Testing of Staff and Residents in Response to an Outbreak

- An outbreak is defined as a new COVID-19 infection in any healthcare personnel (HCP) or any nursing home-onset COVID-19 infection in a resident. In an outbreak investigation, rapid identification and isolation of new cases is critical in stopping further viral transmission. A resident who is admitted to the facility with COVID-19 does not constitute a facility outbreak.

Testing of staff continued

- Upon identification of a single new case of COVID-19 infection in any staff or residents, all staff and residents should be tested, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. See CDC guidance "Testing Guidelines for Nursing Homes" section Non-diagnostic testing of asymptomatic residents without known or suspected exposure to an individual infected with SARS-CoV-2.

Testing of staff continued….

- For individuals who test positive for COVID-19, repeat testing is not recommended. A symptom-based strategy is intended to replace the need for repeated testing. Facilities should follow the CDC guidance Test-Based Strategy for Discontinuing Transmission-Based PrecautionsDiscontinuing Transmission-Based Precautions for residents and Criteria for Return to Work for Healthcare Personnel with SARS-CoV2 Infection.

Routine Testing of Staff

- Routine testing should be based on the extent of the virus in the community, therefore facilities should use their county positivity rate in the prior week as the trigger for staff testing frequency. Reports of COVID-19 county-level positivity rates will be available on the following website by August 28, 2020 (see section titled, "COVID-19 Testing"): https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg

Table 2 Routine Testing Intervals Vary by Community Covid-19 Activity Level

Community Activity COVID 19	County Positivity Rate in the past Week	Minimum Testing Frequency
Low	<5%	Once a Month
Medium	5%-10%	Once a Week
High	>10%	Twice a Week
***This Frequency presumes availability of Point of Care testing on site at the nursing home or where off site testing turnaround time is <48 hours.**	**If the 48-hour turn-around time cannot be met due to community testing supply shortages, limited access or inability of laboratories to process tests within 48 hours, the facility should have documentation of its efforts to obtain quick turnaround test**	

Testing Table Information

The facility should begin testing all staff at the frequency prescribed in the Routine Testing table based on the county positivity rate reported in the past week. Facilities should monitor their county positivity rate every other week (e.g., first and third Monday of every month) and adjust the frequency of performing staff testing according to the table above.

If the county positivity rate increases to a higher level of activity, the facility should begin testing staff at the frequency shown in the table above as soon as the criteria for the higher activity are met.

If the county positivity rate decreases to a lower level of activity, the facility should continue testing staff at the higher frequency level until the county positivity rate has remained at the lower activity level for at least two weeks before reducing testing frequency.

Table 2

- The guidance above represents the minimum testing expected. Facilities may consider other factors, such as the positivity rate in an adjacent (i.e., neighboring) county to test at a frequency that is higher than required. For example, if a facility in a county with low a positivity rate has many staff that live in a county with a medium positivity rate, the facility should consider testing based on the higher positivity rate (in scenario described, weekly staff testing would be indicated).
- State and local officials may also direct facilities to monitor other factors that increase the risk for COVID-19 transmission, such as rates of Emergency Department visits of individuals with COVID-19-like symptoms. Facilities should consult with state and local officials on these factors, and the actions that should be taken to reduce the spread of the virus. https://www.cdc.gov/covid-data-tracker/index.html#ed-visits.

NOTE

- NOTE: Routine testing of asymptomatic residents is not recommended unless prompted by a change in circumstances, such as the identification of a confirmed COVID-19 case in the facility. Facilities may consider testing asymptomatic residents who leave the facility frequently, such as for dialysis or chemotherapy. Facilities should inform resident transportation services (such as non-emergency medical transportation) and receiving healthcare providers (such as hospitals) regarding a resident's COVID-19 status to ensure appropriate infection control precautions are followed.

Routine Testing Continued….

- Routine communication between the nursing home and other entities about the resident's status should ideally occur prior to the resident leaving the nursing home for treatment. Coordination between the nursing home and the other healthcare entity is vital to ensure healthcare staff are informed of the most up to date information relating to the resident's health status, including COVID-19 status, and to allow for proper planning of care and operations. Additionally, facilities should maintain communications with the local ambulance and other contracted providers that transport residents between facilities, to ensure appropriate infection control precautions are followed as described by the CDC.

Refusal of Testing: Staff

- Facilities must have procedures in place to address staff who refuse testing. Procedures should ensure that staff who have signs or symptoms of COVID-19 and refuse testing are prohibited from entering the building until the return to work criteria are met. If outbreak testing has been triggered and a staff member refuses testing, the staff member should be restricted from the building until the procedures for outbreak testing have been completed. The facility should follow its occupational health and local jurisdiction policies with respect to any asymptomatic staff who refuse routine testing.

Refusal of Testing Resident or (RP)

- Residents (or resident representatives) may exercise their right to decline COVID-19 testing in accordance with the requirements under 42 CFR § 483.10(c)(6). In discussing testing with residents, staff should use person-centered approaches when explaining the importance of testing for COVID-19.
- Facilities must have procedures in place to address residents who refuse testing. Procedures should ensure that residents who have signs or symptoms of COVID-19 and refuse testing are placed on TBP until the criteria for discontinuing TBP have been met.
- If outbreak testing has been triggered and an asymptomatic resident refuses testing, the facility should be extremely vigilant, such as through additional monitoring, to ensure the resident maintains appropriate distance from other residents, wears a face covering, and practices effective hand hygiene until the procedures for outbreak testing have been completed.

Other Testing Considerations

- In keeping with current CDC recommendations staff and residents who have recovered from COVID-19 and are asymptomatic do not need to be retested for COVID-19 within 3 months after symptom onset. Until more is known, testing should be encouraged again (e.g., in response to an exposure) 3 months after the date of symptom onset with the prior infection. Facilities should continue to monitor the CDC webpages and FAQs for the latest information. The facility should consult with infectious diseases specialists and public health authorities to review all available information (e.g., medical history, time from initial positive test,

Other Testing Considerations

- Reverse Transcription-Polymerase Chain Reaction Cycle Threshold (RT-PCR Ct) values, and presence of COVID-19 signs or symptoms). Individuals who are determined to be potentially infectious should undergo evaluation and remain isolated until they meet criteria for discontinuation of isolation or discontinuation of transmission-based precautions, depending on their circumstances.
- For residents or staff who test positive, facilities should contact the appropriate state or local entity for contact tracing.
- While not required, facilities may test residents' visitors to help facilitate visitation while also preventing the spread of COVID-19. Facilities should prioritize resident and staff testing and have adequate testing supplies to meet required testing, prior to testing resident visitors.

Conducting Testing

- In accordance with 42 CFR § 483.50(a)(2)(i), the facility must obtain an order from a physician, physician assistant, nurse practitioner, or clinical nurse specialist in accordance with State law, including scope of practice laws to provide or obtain laboratory services for a resident, which includes COVID-19 testing (see F773). This may be accomplished through the use of physician approved policies (e.g., standing orders), or other means as specified by scope of practice laws and facility policy.
- NOTE: Concerns related to orders for laboratory and/or POC testing should be investigated under F773. NC State Law has a standing PRN order cover the testing

Conducting Testing

- A diagnostic test shows if a patient has an active coronavirus infection. As of the date of this guidance, there are two types of diagnostic tests which detect the active virus – molecular tests, such as RT-PCR tests, that detect the virus's genetic material, and antigen tests that detect specific proteins on the surface of the virus. An antibody test looks for antibodies that are made by the immune system in response to a threat, such as a specific virus. An antibody test does not identify an active coronavirus infection; therefore, conducting an antibody test on a staff or resident would not meet the requirements under this regulation.
- Frequently asked questions related to the use of these testing devices in high-risk congregate
- settings such as nursing homes can be found here. In addition, when testing residents, a facility's selection of a test should be person-centered.

Conducting Testing

Rapid POC Testing devices are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance. Accordingly, the facility must have an order from a healthcare professional or pharmacist, as previously described, to perform a rapid POC COVID-19 test on an individual.

Facilities must conduct testing according to nationally recognized guidelines, outlined by the Centers for Disease Control and Prevention (CDC). This would include the following guidelines:

• Preparing for COVID-19 in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html.

• Testing Guidelines for Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html.

- Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-widetesting.html.
- Interim Guidance on Testing Healthcare Personnel for SARS-CoV2: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-healthcare-personnel.html.

Conducting Testing

Collecting and handling specimens correctly and safely is imperative to ensure the accuracy of test results and prevent any unnecessary exposures. The specimen should be collected and, if necessary, stored in accordance with the manufacturer's instructions for use for the test and CDC guidelines.

During specimen collection, facilities must maintain proper infection control and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

The CDC has provided guidance on proper specimen collection:

- See section "Recommendations for conducting swabbing" under CDC's "Considerations for Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes": https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-widetesting.html.
- Influenza Specimen Collection: https://www.cdc.gov/flu/pdf/professionals/flu-specimencollection-poster.pdf.
- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19): (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).
- CDC's Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID19): https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafetyguidelines.html#decentralized.
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafetyguidelines.html.

Conducting Testing

- For additional considerations for antigen testing, see CDC's Interim Guidance for Rapid Antigen Testing for SARS-CoV-2.
- As a reminder, per 42 CFR § 483.50(a), the facility must provide or obtain laboratory services to meet the needs of its residents. If a facility provides its own laboratory services or performs any laboratory tests directly (e.g., SARS-CoV-2 point-of-care test) the provisions of 42 CFR Part 493 apply and the facility must have a current CLIA certificate appropriate for the level of testing performed within the facility. Surveyors should only verify that the facility has a current CLIA certificate and not attempt to determine compliance with the requirements in 42 CFR Part 493.

Reporting Test Results

- Facilities conducting tests under a CLIA certificate of waiver are subject to regulations that require laboratories to report data for all testing completed, for each individual tested. For additional information on reporting requirements see:
- Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes
- Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements

For Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Reporting Test Results

- Surveyors should report concerns related to CLIA certificates or laboratory reporting requirements to the CMS Division of Clinical Laboratory Improvement and Quality at LabExcellence@cms.hhs.gov. When reporting concerns include the CLIA number; name and address of laboratory (facility); number of days that results were not reported, if known; and number of results not reported, if known.
- In addition to reporting in accordance with CLIA requirements, facilities must continue to report COVID-19 information to the CDC's National Healthcare Safety Network (NHSN), in accordance with 42 CFR § 483.80(g)(1)–(2). See "Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes," CMS Memorandum QSO-20-29-NH (May 6, 2020).
- NOTE: Concerns related to informing residents, their representatives and families of new or suspected cases of COVID-19 should be investigated under F885.
- NOTE: Concerns related to the reporting to state and local public health authority of communicable diseases and outbreaks, including for purposes such as contact tracing, should be investigated under F880.

Documentation of Testing

Facilities must demonstrate compliance with the testing requirements. To do so, facilities should do the following:

- For symptomatic residents and staff, document the date(s) and time(s) of the identification of signs or symptoms, when testing was conducted, when results were obtained, and the actions the facility took based on the results.
- Upon identification of a new COVID-19 case in the facility (i.e., outbreak), document the date the case was identified, the date that all other residents and staff are tested, the dates that staff and residents who tested negative are retested, and the results of all tests. All residents and staff that tested negative are expected to be retested until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result (see section Testing of Staff and Residents in response to an outbreak above).

Documentation of Testing

For staff routine testing, document the facility's county positivity rate, the corresponding testing frequency indicated (e.g., every other week), and the date each positivity rate was collected. Also, document the date(s) that testing was performed for all staff, and the results of each test.

Document the facility's procedures for addressing residents and staff that refuse testing or are unable to be tested, and document any staff or residents who refused or were unable to be tested and how the facility addressed those cases.

When necessary, such as in emergencies due to testing supply shortages, document that the facility contacted state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

Documentation

- Facilities may document the conducting of tests in a variety of ways, such as a log of county positivity rates, schedules of completed testing, and/or staff and resident records. However, the results of tests must be done in accordance with standards for protected health information. For residents, the facility must document testing results in the medical record. For staff, including individuals providing services under arrangement and volunteers, the facility must document testing results in a secure manner consistent with requirements specified in 483.80(h)(3).

Surveying for Compliance

Compliance will be assessed through the following process using the COVID-19 Focused Survey for Nursing Homes:

- Surveyors will ask for the facility's documentation noted in the "Documentation of Testing" section above, and review the documentation for compliance.
- Surveyors will also review records of those residents and staff selected as a sample as part of the survey process.

Surveying for compliance

- If possible, surveyors should observe how the facility conducts testing in real-time. In this process, surveyors will assess if the facility is conducting testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests, such as ensuring PPE is used correctly to prevent the transmission of the virus. If observation is not possible, surveyors should interview an individual responsible for testing and inquire on how testing is conducted (e.g., "what are the steps taken to conduct each test?").
- 4. If the facility has a shortage of testing supplies, or cannot obtain test results within 48 hours, the surveyor should ask for documentation that the facility contacted state and local health departments to assist with these issues.

Surveying for compliance

- Facilities that do not comply with the testing requirements in § 483.80(h) will be cited for noncompliance at F886. Additionally, enforcement remedies (such as civil money penalties) will be imposed based on the resident outcome (i.e., the scope and severity of the noncompliance), in accordance with Chapter 7 of the State Operations Manual.

Surveying for compliance

If the facility has documentation that demonstrates their attempts to perform and/or obtain testing in accordance with these guidelines (e.g., timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours), surveyors should not cite the facility for noncompliance. Surveyors should also inform the state or local health authority of the facility's lack of resources.

CMS is also continuing to assess automated methods for determining compliance with the testing requirements, which may augment the assessment of compliance through onsite surveys.

Surveying for compliance

- Clinical Questions about COVID-19: Questions and Answers- Testing in Nursing Homes https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes
- Nursing Home Reopening Recommendations for State and Local Officials https://www.cms.gov/files/document/qso-20-30-nh.pdf-0
- Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings
- https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html

Covid-19 Focused Survey for Nursing Home

- CMS is revising the COVID-19 Focused Survey for Nursing Homes tool to reflect the new testing requirements implemented in the IFC, as well as other updates to help ensure an effective assessment of the facility's compliance, such as selecting a number of residents as a sample to review the facility's application of the standards on that sample, and that a facility is implementing the appropriate infection prevention standards (e.g., transmission-based precautions, face coverings, etc.). We are also revising the survey process to include the assessment of compliance with the requirements for facilities to designate one or more individuals as the infection preventionist(s) (IPs) who are responsible for the facility's infection prevention and control program at 42 CFR § 483.80(b). Noncompliance related to this requirement will be cited at tag F882.

Visitation QSO-20-39

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).

- **Visitation Guidance:** CMS is issuing new guidance for visitation in nursing homes during the COVID-19 PHE. The guidance below provides reasonable ways a nursing home can safely facilitate in-person visitation to address the psychosocial needs of residents.
- **Use of Civil Money Penalty (CMP) Funds:** CMS will now approve the use of CMP funds to purchase tents for outdoor visitation and/or clear dividers (e.g., Plexiglas or similar products) to create physical barriers to reduce the risk of transmission during in-person visits

CMS is revising the guidance regarding visitation in nursing homes during the COVID-19 PHE. The information contained in this memorandum supersedes and replaces previously issued guidance and recommendations regarding visitation.

Guidance

- Visitation can be conducted through different means based on a facility's structure and residents' needs, such as in resident rooms, dedicated visitation spaces, outdoors, and for circumstances beyond compassionate care situations. Regardless of how visits are conducted, there are certain core principles and best practices that reduce the risk of COVID-19 transmission:

Core Principles of COVID-19 Infection Prevention

• Screening of all who enter the facility for signs and symptoms of COVID-19 (e.g., temperature checks, questions or observations about signs or symptoms), and denial of entry of those with signs or symptoms

• Hand hygiene (use of alcohol-based hand rub is preferred)

• Face covering or mask (covering mouth and nose)

• Social distancing at least six feet between persons • Instructional signage throughout the facility and proper visitor education on COVID-19 signs and symptoms, infection control precautions, other applicable facility practices (e.g., use of face covering or mask, specified entries, exits and routes to designated areas, hand hygiene)

• Cleaning and disinfecting high frequency touched surfaces in the facility often, and designated visitation areas after each visit

• Appropriate staff use of Personal Protective Equipment (PPE)

• Effective cohorting of residents (e.g., separate areas dedicated COVID-19 care)

• Resident and staff testing conducted as required at 42 CFR 483.80(h) (see QSO-20-38-NH)

Core Principles continued….

• These core principles are consistent with the Centers for Disease Control and Prevention (CDC) guidance for nursing homes, and should be adhered to at all times. Additionally, visitation should be person-centered, consider the residents' physical, mental, and psychosocial well-being, and support their quality of life. The risk of transmission can be further reduced through the use of physical barriers (e.g., clear Plexiglas dividers, curtains). Also, nursing homes should enable visits to be conducted with an adequate degree of privacy. Visitors who are unable to adhere to the core principles of COVID-19 infection prevention should not be permitted to visit or should be asked to leave. By following a person-centered approach and adhering to these core principles, visitation can occur safely based on the below guidance.

Outdoor Visitation

• While taking a person-centered approach and adhering to the core principles of COVID-19 infection prevention, outdoor visitation is preferred and can also be conducted in a manner that reduces the risk of transmission. Outdoor visits pose a lower risk of transmission due to increased space and airflow. Therefore, all visits should be held outdoors whenever practicable. Aside from weather considerations (e.g., inclement weather, excessively hot or cold temperatures, poor air quality), an individual resident's health status (e.g., medical condition(s), COVID-19 status), or a facility's outbreak status, outdoor visitation should be facilitated routinely. Facilities should create accessible and safe outdoor spaces for visitation, such as in courtyards, patios, or parking lots, including the use of tents, if available. When conducting outdoor visitation, facilities should have a process to limit the number and size of visits occurring simultaneously to support safe infection prevention actions (e.g., maintaining social distancing). We also recommend reasonable limits on the number of individuals visiting with any one resident at the same time.

Indoor Visitation

Facilities should accommodate and support indoor visitation, including visits for reasons beyond compassionate care situations, based on the following guidelines:

a) There has been no new onset of COVID-19 cases in the last 14 days and the facility is not currently conducting outbreak testing;

b) Visitors should be able to adhere to the core principles and staff should provide monitoring for those who may have difficulty adhering to core principles, such as children;

c) Facilities should limit the number of visitors per resident at one time and limit the total number of visitors in the facility at one time (based on the size of the building and physical space). Facilities should consider scheduling visits for a specified length of time to help ensure all residents are able to receive visitors; and

d) Facilities should limit movement in the facility. For example, visitors should not walk around different halls of the facility. Rather, they should go directly to the resident's room or designated visitation area. Visits for residents who share a room should not be conducted in the resident's room.

Indoor Visitation

• NOTE: For situations where there is a roommate and the health status of the resident prevents leaving the room, facilities should attempt to enable in-room visitation while adhering to the core principles of COVID-19 infection prevention.

Indoor Visitation

Facilities should use the COVID-19 county positivity rate, found on the COVID-19 Nursing Home Data site as additional information to determine how to facilitate indoor visitation:

• Low (<5%) = Visitation should occur according to the core principles of COVID-19 infection prevention and facility policies (beyond compassionate care visits)

• Medium (5% – 10%) = Visitation should occur according to the core principles of COVID-19 infection prevention and facility policies (beyond compassionate care visits)

• High (>10%) = Visitation should only occur for compassionate care situations according to the core principles of COVID-19 infection prevention and facility policies

Indoor Visitation

- Facilities may also monitor other factors to understand the level of COVID-19 risk, such as rates of COVID-19-Like Illness2 visits to the emergency department or the positivity rate of a county adjacent to the county where the nursing home is located. We note that county positivity rate does not need to be considered for outdoor visitation.
- We understand that some states or facilities have designated categories of visitors, such as "essential caregivers," based on their visit history or resident designation. CMS does not distinguish between these types of visitors and other visitors. Using a person-centered approach when applying this guidance should cover all types of visitors, including those who have been categorized as "essential caregivers."

Visitor Testing

- While not required, we encourage facilities in medium or high-positivity counties to test visitors, if feasible. If so, facilities should prioritize visitors that visit regularly (e.g., weekly), although any visitor can be tested. Facilities may also encourage visitors to be tested on their own prior to coming to the facility (e.g., within 2–3 days) with proof of negative test results and date of test.

****Facilities can not require visitors to have covid negative tests to visit

Compassionate Care Visits

While end-of-life situations have been used as examples of compassionate care situations, the term "compassionate care situations" does not exclusively refer to end-of-life situations. Examples of other types of compassionate care situations include, but are not limited to:

- A resident, who was living with their family before recently being admitted to a nursing home, is struggling with the change in environment and lack of physical family support.
- A resident who is grieving after a friend or family member recently passed away.
- A resident who needs cueing and encouragement with eating or drinking, previously provided by family and/or caregiver(s), is experiencing weight loss or dehydration.
- A resident, who used to talk and interact with others, is experiencing emotional distress, seldom speaking, or crying more frequently (when the resident had rarely cried in the past).

Compassionate Care Visits

- Allowing a visit in these situations would be consistent with the intent of, "compassionate care situations." Also, in addition to family members, compassionate care visits can be conducted by any individual that can meet the resident's needs, such as clergy or lay persons offering religious and spiritual support. Furthermore, the above list is not an exhaustive list as there may be other compassionate care situations not included.
- Lastly, at all times, visits should be conducted using social distancing; however, if during a compassionate care visit, a visitor and facility identify a way to allow for personal contact, it should only be done following all appropriate infection prevention guidelines, and for a limited amount of time. Through a person-centered approach, facilities should work with residents, families, caregivers, resident representatives, and the Ombudsman program to identify the need for compassionate care visits.

Required Visitation

- We believe the guidance above represents reasonable ways a nursing home can facilitate in-person visitation. Except for on-going use of virtual visits, facilities may still restrict visitation due to the COVID-19 county positivity rate, the facility's COVID-19 status, a resident's COVID-19 status, visitor symptoms, lack of adherence to proper infection control practices, or other relevant factor related to the COVID-19 PHE. However, facilities may not restrict visitation without a reasonable clinical or safety cause, consistent with §483.10(f)(4)(v). For example, if a facility has had no COVID-19 cases in the last 14 days and its county positivity rate is low or medium, a nursing home **must** facilitate in-person visitation consistent with the regulations, which can be done by applying the guidance stated above. Failure to facilitate visitation, without adequate reason related to clinical necessity or resident safety, would constitute a potential violation of 42 CFR 483.10(f)(4), and the facility would be subject to citation and enforcement actions.

Required Visitation

- Residents who are on transmission-based precautions for COVID-19 should only receive visits that are virtual, through windows, or in-person for **compassionate care situations**, with adherence to transmission-based precautions. However, this restriction should be lifted once transmission-based precautions are no longer required per CDC guidelines, and other visits may be conducted as described above.

F 882: Review of Infection Preventionist

Access to the Long-Term Care Ombudsman

As stated in previous CMS guidance QSO-20-28-NH (revised), regulations at 42 CFR 483.10(f)(4)(i)(C) require that a Medicare and Medicaid certified nursing home provide representatives of the Office of the State Long-Term Care Ombudsman with immediate access to any resident.

During this PHE, in-person access may be limited due to infection control concerns and/or transmission of COVID-19; however, in-person access may not be limited without reasonable cause. We note that representatives of the Office of the Ombudsman should adhere to the core principles of COVID-19 infection prevention.

If in-person access is not advisable, such as the Ombudsman having signs or symptoms of COVID-19, facilities must, at a minimum, facilitate alternative resident communication with the ombudsman, such as by phone or through use of other technology.

Nursing homes are also required under 42 CFR 483.10(h)(3)(ii) to allow the Ombudsman to examine the resident's medical, social, and administrative records as otherwise authorized by State law.

Federal Disability Rights Laws and Protection & Advocacy (P&A) Programs

Section 483.10(f)(4)(i)(E) and (F) requires the facility to allow immediate access to a resident by any representative of the protection and advocacy systems, as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), and of the agency responsible for the protection and advocacy system for individuals with a mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000). P&A programs authorized under the DD Act protect the rights of individuals with developmental and other disabilities and are authorized to "investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported or if there is probably cause to believe the incidents occurred." 42 U.S.C. § 15043(a)(2)(B). Under its federal authorities, representatives of P&A programs are permitted access to all facility residents, which includes "the opportunity to meet and communicate privately with such individuals regularly, both formally and informally, by telephone, mail and in person." 42 CFR 51.42(c); 45 CFR 1326.27.

Disability Rights continued…..

- Additionally, each facility must comply with federal disability rights laws such as Section 504 of the Rehabilitation Act and the Americans with Disabilities Act (ADA). For example, if a resident requires assistance to ensure effective communication (e.g., a qualified interpreter or someone to facilitate communication) and the assistance is not available by onsite staff or effective communication cannot be provided without such entry (e.g., video remote interpreting), the facility must allow the individual entry into the nursing home to interpret or facilitate, with some exceptions. This would not preclude nursing homes from imposing legitimate safety measures that are necessary for safe operations, such as requiring such individuals to adhere to the core principles of COVID-19 infection prevention.

Entry of Health Care Workers and Other Providers of Services

- Health care workers who are not employees of the facility but provide direct care to the facility's residents, such as hospice workers, Emergency Medical Services (EMS) personnel, dialysis technicians, laboratory technicians, radiology technicians, social workers, clergy etc., must be permitted to come into the facility as long as they are not subject to a work exclusion due to an exposure to COVID-19 or show signs or symptoms of COVID-19 after being screened. We note that EMS personnel do not need to be screened so they can attend to an emergency without delay. We remind facilities that all staff, including individuals providing services under arrangement as well as volunteers, should adhere to the core principles of COVID-19 infection prevention and must comply with COVID-19 testing requirements.

Communal Activities and Dining

- While adhering to the core principles of COVID-19 infection prevention, communal activities and dining may occur. Residents may eat in the same room with social distancing (e.g., limited number of people at each table and with at least six feet between each person).
- Facilities should consider additional limitations based on status of COVID-19 infections in the facility. Additionally, group activities may also be facilitated (for residents who have fully recovered from COVID-19, and for those not in isolation for observation, or with suspected or confirmed COVID-19 status) with social distancing among residents, appropriate hand hygiene, and use of a face covering.
- Facilities may be able to offer a variety of activities while also taking necessary precautions. For example, book clubs, crafts, movies, exercise, and bingo are all activities that can be facilitated with alterations to adhere to the guidelines for preventing transmission.

Survey Considerations

• For concerns related to resident communication with and access to persons and services inside and outside the facility, surveyors should investigate for non-compliance at 42 CFR 483.10(b), F550.

• For concerns related to a facility limiting visitors without a reasonable clinical and safety cause, surveyors should investigate for non-compliance at 42 CFR 483.10(f)(4), F563.

• For concerns related to ombudsman access to the resident and the resident's medical record, surveyors should investigate for non-compliance at 42 CFR 483.10(f)(4)(i)(C), F562 and 483.10(h)(3)(ii), F583.

• For concerns related to lack of adherence to infection control practices, surveyors should investigate for non-compliance at 42 CFR 483.80(a), F880.

Use of CMP Funds to Aid in Visitation

- Technology can help improve social connections for some residents by helping to support and maintain relationships with loved ones. CMS has previously approved the use of CMP funds (See QSO-20-28-NH) to purchase communicative devices, such as tablets or webcams, to increase the ability for nursing homes to help residents stay connected with their loved ones. To ensure a balanced distribution of funds, facilities are limited to purchase one communicative device per 7–10 residents, up to a maximum of $3,000 per facility.
- Additionally, facilities may apply to use CMP funds to help facilitate in-person visits. CMS will now approve the use of CMP funds to purchase tents for outdoor visitation and/or clear dividers (e.g., Plexiglas or similar product) to create a physical barrier to reduce the risk of transmission during in-person visits. Funding for tents and clear dividers is also limited to a maximum of $3,000 per facility. NOTE: When installing tents, facilities need to ensure appropriate life safety code requirements found at 42 CFR 483.90 are met, unless waived under the PHE declaration.
- To apply to receive CMP funds for communicative devices, tents, or clear dividers, please contact your state agency's CMP contact.

Upgrade SAMS Access to Utilize New Point of Care Laboratory Reporting Pathway in NHSN

- CDC's National Healthcare Safety Network will release a new reporting pathway on October 15, 2020 to help nursing homes and long-term care facilities comply with SARS-CoV-2 point of care laboratory test reporting requirements.
- Using the pathway will require an upgraded SAMS access from level 1 to 3.
- Be on the lookout for an email invitation from CDC to perform this upgrade.
- Any nursing home or long-term care facility that would like to upgrade now can email nhsn@cdc.gov.