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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-38-NH

DATE: **August 26, 2020** REVISED 09/23/2022 **& 05/08/2023**
EXPIRED 05/11/2023

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements**

Effective 05/11/2023, this memo is no longer in effect. Testing for COVID-19 should be conducted by following accepted national standards, such as CDC recommendations. Noncompliance related to COVID-19 testing will be cited at F-tag 880. More information on the requirements regarding the identification of infections and communicable diseases can be found in Appendix PP of the State Operations Manual, F880 (42 CFR §483.80(a)(1) and §483.80(a)(2)(i)).

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities continue to respond effectively to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On August 25, 2020, CMS published an interim final rule with comment period (IFC). This rule establishes **Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents.** Specifically, facilities are required to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the HHS Secretary. This memorandum provides guidance for facilities to meet the new requirements.
- *Routine testing of asymptomatic staff is no longer recommended but may be performed at the discretion of the facility.*
- *Updated recommendations for testing individuals who have recovered from COVID-19.*

On August 25, 2020, CMS published an interim final rule with comment period (IFC), CMS-3401-IFC, entitled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments of 1988 (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency". 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.

§ 483.80 Infection control

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§ 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:

(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 diagnosed with COVID-19 in the facility;

(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.

(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.

(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.

F886

DEFINITIONS

"Close contact " refers to someone who has been within 6 feet of a COVID-19 positive person for a cumulative total of 15 minutes or more over a 24-hour period.

"Higher-risk exposure" refers to exposure of an individual's eyes, nose, or mouth to material potentially containing SARS-CoV-2, particularly if present in the room for an aerosol-generating procedure. This can occur when staff do not wear adequate personal protective equipment during care or interaction with an individual. For more information, see CDC's "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2."

GUIDANCE

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, at a minimum, a CLIA Certificate of Waiver. Information on obtaining a CLIA Certificate of Waiver can be found here.

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.

"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.

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 investigation (as specified below).

Instruct facility staff, regardless of their vaccination status, to report any of the following criteria to occupational health or another point of contact designated by the facility so they can be properly managed:

- *a positive viral test for SARS-CoV-2,*
- *symptoms of COVID-19, or*
- *a higher-risk exposure to someone with SARS-CoV-2 infection*

Table 1: Testing Summary

Testing Trigger	Staff	Residents
Symptomatic individual identified	Staff, regardless of vaccination status, with signs or symptoms must be tested.	Residents, regardless of vaccination status, with signs or symptoms must be tested.
Newly identified COVID-19 positive staff or resident in a facility that can identify close contacts	Test all staff, regardless of vaccination status, that had a higher-risk exposure with a COVID-19 positive individual.	Test all residents, regardless of vaccination status, that had close contact with a COVID-19 positive individual.
Newly identified COVID-19 positive staff or resident in a facility that is unable to identify close contacts	Test all staff, regardless of vaccination status, facility-wide or at a group level if staff are assigned to a specific location where the new case occurred (e.g., unit, floor, or other specific area(s) of the facility).	Test all residents, regardless of vaccination status, facility-wide or at a group level (e.g., unit, floor, or other specific area(s) of the facility).
Routine testing	*Not generally recommended*	Not generally recommended

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

Staff with symptoms or signs of COVID-19, regardless of vaccination status, must be tested *as soon as possible* 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) guidance "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2." 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, regardless of vaccination status, must be tested *as soon as possible*. 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 with a Higher-Risk Exposure and Residents who had a Close Contact

For information on testing staff with a higher-risk exposure to COVID-19 and residents who had close contact with a COVID-19 positive individual, when the facility is not in an outbreak status, see the CDC's "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic" and "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2." Examples may include exposures from a visitor, while on a leave of absence, or during care of a resident on the COVID-19 unit.

Testing of Staff and Residents During an Outbreak Investigation

An outbreak investigation is initiated when a single new case of COVID-19 occurs among residents or staff to determine if others have been exposed. An outbreak investigation would not be triggered when a resident with known COVID-19 is admitted directly into TBP, or when a resident known to have close contact with someone with COVID-19 is admitted directly into TBP and develops COVID-19 before TBP are discontinued. In an outbreak investigation, rapid identification and isolation of new cases is critical in stopping further viral transmission.

Upon identification of a single new case of COVID-19 infection in any staff or residents, testing should begin immediately *(but not earlier than 24 hours after the exposure, if known)*. Facilities have the option to perform outbreak testing through two approaches, contact tracing or broad-based (e.g. facility-wide) testing.

If the facility has the ability to identify close contacts of the individual with COVID-19, they could choose to conduct focused testing based on known close contacts. If a facility does not have the expertise, resources, or ability to identify all close contacts, they should instead investigate the outbreak at a facility-wide or group-level (e.g., unit, floor, or other specific area(s) of the facility). Broader approaches might also be required if the facility is directed to do so by the jurisdiction's public health authority, or in situations where all potential contacts are unable to be identified, are too numerous to manage, or when contact tracing fails to halt transmission.

For further information on contact tracing and broad-based testing, including frequency of repeat testing, see CDC guidance "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic"

For individuals who test positive for COVID-19, facilities should follow the CDC "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic" guidance for *discontinuing TBP for* residents and the "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2." for staff.

Routine Testing of Staff

Routine screening testing of asymptomatic staff is no longer recommended but may be perfiormed at the discretion of the facility. See the CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic guidance for additional information.

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.

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 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.

Resident Testing – New Admissions

For testing information of residents who are newly admitted or readmitted to the facility and those who leave the facility for 24 hours or longer, see the Managing admissions and residents who leave the facility section of the CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic webpage.

Refusal of Testing

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 refuses routine testing.

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 refuse testing *managed in accordance with the CDC guidance for use of TBP.*

Clinical discussions about testing may include alternative specimen collection sources that may be more acceptable to residents than nasopharyngeal swabs (e.g., anterior nares). Providing information about the method of testing and reason for pursuing testing may facilitate discussions with residents or resident representatives.

Other Testing Considerations

In general, testing is not necessary for asymptomatic people who have recovered from SARS-CoV-2 infection in the prior *30* days; *testing should be considered for those who have recovered in the prior 31-90 days* however, if testing is performed on these people, an antigen test instead of a nucleic acid amplification test (NAAT) is recommended. This is because some people may remain NAAT positive but not be infectious during this period. Facilities should continue to monitor *CMS and CDC guidance* and FAQs for the latest information. For residents or staff who test positive, facilities should *follow the guidance in the Testing Staff and Residents During an Outbreak section above and* contact the appropriate state or local entity for contact tracing.

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.

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.

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 *on the CMS Current Emergencies webpage, in the For Labs section*. In addition, when testing residents, a facility's selection of a test should be person-centered.

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 a NIOSH-approved N95 or equivalent 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:

- 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 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

For additional considerations for antigen testing, see CDC's Perform SARS-CoV-2 Viral Testing

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 are required to have a CLIA certificate and are subject to regulations that require laboratories to report results for all testing completed, for each individual tested, to state or local health departments. For additional information on reporting requirements see:

- Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes
- CMS memorandum: 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

Surveyors should report concerns related to CLIA certificates or laboratory reporting requirements to their CLIA State Agency contact. 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, document the date the case was identified, the date that other residents and staff are tested, the dates that staff and residents who tested negative are retested, and the results of all tests (see section "Testing of Staff and Residents During an Outbreak Investigation" above).
- 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.

Facilities may document the conducting of tests in a variety of ways, such as a log of community transmission levels, 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 and during the Standard Survey for Nursing Homes:

1. Surveyors will ask for the facility's documentation noted in the "Documentation of Testing" section above, and review the documentation for compliance.
2. Surveyors will also review records of those residents and staff selected as a sample as part of the survey process.
3. 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.

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.

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.

The current Survey/Infection Prevention, Control & Immunization Pathway (CMS-20054) can be found in the LTC Survey Pathways zipfile located at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes

Contact: Questions related to the nursing home testing requirement may be submitted to: DNH_TriageTeam@cms.hhs.gov.

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

/s/
David R. Wright