



Center for Clinical Standards and Quality/Survey & Certification Group

DATE: August 26, 2020 **Ref: QSO-20-38-NH**
REVISED 09/10/2021

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**

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.
- *Revised COVID-19 staff testing is based on the facility’s county level of community transmission instead of county test positivity rate. The frequency of testing has also been updated.*
- *Facilities now have two options to conduct outbreak testing, through either a contact tracing or broad-based testing approach.*

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.**

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.

“Level of community transmission” refers to facility’s county level of COVID-19 transmission. This metric uses two indicators for categorization (1. Total number of new cases per 100,000 persons within the last 7 days and 2. Percentage of positive diagnostic and screening nucleic acid amplification tests (NAAT) during the last 7 days), which can be found on the Centers for Disease Control and Prevention (CDC) COVID-19 Integrated County View site at <https://covid.cdc.gov/covid-data-tracker/#county-view>.

“Fully vaccinated” refers to the CDC definition. The current definition can be found on CDC’s website: [Interim Public Health Recommendations for Fully Vaccinated People | CDC](#).

“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.”](#)

“Unvaccinated” refers to a person who does not fit the definition of “fully vaccinated,” including people whose vaccination status is not known, for the purposes of this guidance.

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).

Table 1: Testing Summary

Testing Trigger	Staff	Residents
Symptomatic individual identified	Staff, vaccinated and unvaccinated, with signs <i>or</i> symptoms must be tested.	Residents, vaccinated and unvaccinated, with signs <i>or</i> symptoms must be tested.
<i>Newly identified COVID-19 positive staff or resident in a facility that can identify close contacts</i>	<i>Test all staff, vaccinated and unvaccinated, that had a higher-risk exposure with a COVID-19 positive individual.</i>	<i>Test all residents, vaccinated and unvaccinated, that had close contact with a COVID-19 positive individual.</i>
<i>Newly identified COVID-19 positive staff or resident in a facility that is unable to identify close contacts</i>	<i>Test all staff, vaccinated and unvaccinated, 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).</i>	<i>Test all residents, vaccinated and unvaccinated, facility-wide or at a group level (e.g., unit, floor, or other specific area(s) of the facility).</i>
Routine testing	According to Table 2 below	Not <i>generally</i> recommended

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

Staff with symptoms or signs of COVID-19, vaccinated or not vaccinated, must be tested immediately 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, vaccinated or not vaccinated, must be tested immediately. 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 to Prevent SARS-CoV-2 Spread in Nursing Homes](#)" 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*

A new COVID-19 infection in any *staff* or any [nursing home-onset](#) COVID-19 infection in a resident *triggers an outbreak investigation*. 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.

Upon identification of a single new case of COVID-19 infection in any staff or residents, *testing should begin* immediately. *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 to Prevent SARS-CoV-2 Spread in Nursing Homes](#)."

For individuals who test positive for COVID-19, repeat testing is not recommended *to discontinue TBP or work restrictions*. A symptom-based strategy is intended to replace the need for repeated testing. Facilities should follow the CDC guidance "[Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#)" for residents and "[Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2](#)" for staff.

Routine Testing of Staff

Routine testing of unvaccinated staff should be based on the extent of the virus in the community. Fully vaccinated staff do not have to be routinely tested. Facilities should use their *community transmission level* as the trigger for staff testing frequency. **Reports of COVID-19 level of community transmission are available on the CDC COVID-19 Integrated County View site: <https://covid.cdc.gov/covid-data-tracker/#county-view>. Please see the COVID-19 Testing section on the CMS COVID-19 Nursing Home Data webpage: <https://data.cms.gov/covid-19/covid-19-nursing-home-data> for information on how to obtain current and historic levels of community transmission on the CDC website.**

Table 2: Routine Testing Intervals by *County COVID-19 Level of Community Transmission*

<i>Level of COVID-19 Community Transmission</i>	Minimum Testing Frequency of Unvaccinated Staff⁺
<i>Low (blue)</i>	<i>Not recommended</i>
<i>Moderate (yellow)</i>	<i>Once a week*</i>
<i>Substantial (orange)</i>	<i>Twice a week*</i>
<i>High (red)</i>	<i>Twice a week*</i>

⁺Vaccinated staff do not need *to* be routinely tested.

*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 results with the identified laboratory or laboratories and contact with the local and state health departments.

The facility should test all unvaccinated staff at the frequency prescribed in the Routine Testing table based on the *level of community transmission* reported in the past week. Facilities should monitor their *level of community transmission* 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 *level of community transmission* 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 *level* are met.
- If the *level of community transmission* decreases to a lower level of activity, the facility should continue testing staff at the higher frequency level until the *level of community transmission* has remained at the lower activity level for at least two weeks before reducing testing frequency.

The guidance above represents the minimum testing expected. Facilities may consider other factors, such as the *level of community transmission* 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 a *low level of community transmission* has many staff that live in a county with a *moderate level of community transmission*, the facility should consider testing based on the higher *level of community transmission* (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.

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 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

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 *an unvaccinated* 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 *unvaccinated* staff who refuse 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 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.

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.

Residents who refuse testing may require TBP based on symptoms or vaccination status. For further information, see CDC guidance “[Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes.](#)”

Other Testing Considerations

Although exceptions exist, generally 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, 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.

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 *guidance*:

- Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes:
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html>
- *Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic:*
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

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.

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:

- Influenza Specimen Collection: <https://www.cdc.gov/flu/pdf/professionals/flu-specimen-collection-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 (COVID-19):
<https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>.

For additional considerations for antigen testing, see CDC’s *“SARS-CoV-2 Antigen Testing in Long Term Care Facilities.”*

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).

- For staff routine testing, document the facility’s *level of community transmission*, the corresponding testing frequency indicated (e.g., every week), and the date each *level of community transmission* was collected. Also, document the date(s) that testing was performed for *unvaccinated* 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.

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/Downloads/LTC-Survey-Pathways.zip>.

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