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OPERATIONAL BULLETIN

Bulletin #	Title		Date Issued
#2020-09-16-01	New Rules Issued by Centers for Medicare and Medicaid Services for Long-Term Care Facilities Regarding COVID-19 Testing Requirements		September 16, 2020
Superseded	Released By:	Source:	Page(s)
N/A	Maine EMS	Maine EMS, Maine DHHS, U.S. Centers for Medicare and Medicaid	2 and attachment
Approved By:	J. Sam Hurley, MPH, EMPS, NRP (Maine EMS Director)		

On August 25, 2020, the U.S. Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) published an interim final rule (IFC) entitled: *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 and Revised COVID-19 Focused Survey Tool.*

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 attached memorandum provides guidance for facilities to meet the new requirements.

While the responsibility for compliance with this rule is with the LTC, it does require LTC facilities to test or obtain copies of COVID-19 test results from contractors who provide services to facility residents or have staff who come into contact with facility residents or staff. In the event that an LTC facility reaches out to your service regarding testing, Maine EMS will support any EMS agency that wishes to conduct their own swabbing in house by reviewing the application for authorization as quickly as possible.

This does *not* affect 911-response to LTCs, as negative results are not required for EMS agencies to respond to a 911 activation.

At this time, Maine DHHS' Division of Licensing and Certification has also interpreted this rule as to not apply to organizations that may regularly frequent LTCs for interfacility transports but do not have established contracts with the facility. The DLC has requested clarification regarding the language in the rule; however, the timeline for a response may take several weeks. Therefore,

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it is important to note that this is subject to change pending more information from the U.S. HHS program.

Questions should be directed toward the LTC facilities that your agency serves as they are the parties responsible for compliance with this new federal rule. If there are any additional general questions, please do not hesitate to reach out to Maine EMS and we will do our best to facilitate an answer.

Attachment:

U.S. Centers of Medicare and Medicaid. (August 26, 2020). Memorandum. *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 and Revised COVID-19 Focused Survey Tool.*



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-38-NH

DATE: August 26, 2020

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 and Revised COVID-19 Focused Survey Tool

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 Focused Survey Tool** - To assess compliance with the new testing requirements, CMS has revised the survey tool for surveyors. We are also adding to the survey process the assessment of compliance with the requirements for facilities to designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's infection prevention and control program (IPCP) at 42 CFR § 483.80(b). In addition, we are making a number of revisions to the survey tool to reflect other COVID-19 guidance updates.

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

* * * * *

§ 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.**

GUIDANCE FOR F886

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](#).

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.

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.

*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.

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.](#)

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 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 COVID-19 Activity	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 results with the identified laboratory or laboratories and contact with the local and state health departments.

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.

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: 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 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.

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.

If a resident has [symptoms consistent with COVID-19](#) or has been exposed to COVID-19, or if there is a facility outbreak and the resident declines testing, he or she should be placed on or remain on TBP until he or she meets the symptom-based criteria for discontinuation.

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, 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 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-wide-testing.html>.
- Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-healthcare-personnel.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 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-wide-testing.html>.
- 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#decentralized>.
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories: <https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>.

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](#)

- 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 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).
- 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.

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:

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.

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.

Additional Resource Links:

- 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 Homes

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.

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

Attachments:

COVID-19 Focused Survey for Nursing Homes

COVID-19 Focused Survey for Nursing Homes

Infection Control

This survey tool must be used to investigate compliance at F880, *F882*, F884 (CMS Federal surveyors only), F885, *F886*, and E0024. Surveyors must determine whether the facility is implementing proper infection prevention and control practices to prevent the development and transmission of COVID-19 and other communicable diseases and infections. Entry and screening procedures as well as resident care guidance has varied over the progression of COVID-19 transmission in facilities. Facilities are expected to be in compliance with CMS requirements and surveyors will use guidance that is in effect at the time of the survey. Refer to QSO memos released at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions>.

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

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

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

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

Note: It is imperative that surveyors refer to the most recent information for COVID-19 testing parameters and frequency set forth by the Secretary *described in the guidance for F886*. *County-level data are available on the CDC website:*

<https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg>

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

COVID-19 Focused Survey for Nursing Homes

Surveyor(s) reviews for:

- The overall effectiveness of the Infection Prevention and Control Program (IPCP) including IPCP policies and procedures;
- Standard and Transmission-Based Precautions (*review care of a resident under observation, suspected of, or confirmed to have COVID-19 infection*);
- Quality of resident care practices, including those *under observation, suspected of, and confirmed to have COVID-19 infection*, if applicable;
- The surveillance *and testing* process;
- Visitor entry and facility screening practices;
- Education, monitoring, and screening practices of staff;
- *Actions taken to prevent transmission, such as cohorting and managing care for residents suspected of having or confirmed to have COVID-19*;
- Facility policies and procedures to address staffing issues during emergencies, such as transmission of COVID-19;
- How the facility informs residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility; *and*
- *The infection preventionist role.*

The survey team will select a random sample of three residents, and if not already sampled, add one additional resident who was confirmed COVID-19 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 additional staff who was confirmed COVID-19 positive or had signs or symptoms consistent with COVID-19, for purposes of determining compliance.

1. Standard and Transmission-Based Precautions (TBPs)

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

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guidance for healthcare professionals is located at: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html> and healthcare facilities is located at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/us-healthcare-facilities.html>. Guidance on strategies for optimizing PPE supply is located at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html>. If a surveyor believes a facility should be cited for not having or providing the necessary supplies, the State Agency should contact the CMS Regional Location.

General Standard Precautions:

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

Hand Hygiene:

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

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Personal Protective Equipment (PPE):

- Determine if staff appropriately use PPE including, but not limited to, the following:
 - Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;
 - Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;
 - Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care; and
 - An isolation gown, *eye protection (e.g. 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.*
- Is PPE appropriately removed and discarded after resident care, prior to leaving room (except in the case of extended use of PPE per national/local recommendations), followed by hand hygiene?
- If PPE use is extended/reused, is it done according to national and/or local guidelines? If it is reused, is it cleaned/decontaminated/maintained after and/or between uses?
- Interview appropriate staff to determine if PPE is available, accessible, and used by staff.
 - Are there sufficient PPE supplies available to follow infection prevention and control guidelines? In the event of PPE shortages, what actions is the facility taking to address this issue?
 - Do staff know how to obtain PPE supplies before providing care?
 - Do they know who to contact for replacement supplies?
- Are all staff wearing a facemask (e.g., a cloth face covering can be used by staff where PPE is not indicated, such as administrative staff who are not at risk of coming in contact with infectious materials)?*
- When COVID-19 is present in the facility, are staff wearing an N95 or equivalent or higher-level respirator, instead of a facemask, for aerosol generating procedures?*

Source Control:

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

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

- Determine if appropriate Transmission-Based Precautions are implemented:
 - For a resident on Contact Precautions: staff don gloves and isolation gown before contact with the resident and/or his/her environment;
 - For a resident on Droplet Precautions: staff don a facemask within six feet of a resident;
 - For a resident on Airborne Precautions: staff don an N95 or higher-level respirator prior to room entry of a resident;

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

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

2. Resident Care

- Are 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)?
- When 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?*
- Is 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?*
- Does the facility 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?*
- Does 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 recommendations?*
- For the resident who develops severe symptoms of illness and requires transfer to a hospital for a higher level of care, did the facility alert emergency medical services and the receiving facility of the resident's diagnosis (suspected or confirmed COVID-19) and precautions to be taken by transferring and receiving staff as well as place a facemask *or cloth face covering* on the resident during transfer (*as tolerated*)?
- For residents who need to leave the facility for care (e.g., dialysis), did the facility notify the transportation and receiving health care team of the resident's suspected or confirmed COVID-19 status?

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

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3. IPCP Standards, Policies and Procedures

- Did the facility establish a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19?
- Do the facility's policies or procedures include when to notify local/state public health officials if there are clusters of respiratory illness or cases of COVID-19 that are identified or suspected?
- Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

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

4. Infection Surveillance

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

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

5. Visitor Entry

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

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- Restricting visitation based on federal or state guidance to ensure visitation does not lead to transmission of COVID-19; and
- Signage posted at facility entrances for screening and restrictions as well as a communication plan to alert visitors of new procedures/restrictions.

For those permitted entry, are they instructed to frequently perform hand hygiene; limit their interactions with others in the facility and surfaces touched; restrict their visit to the resident's room or other location(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?

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

6. Education, Monitoring, and Screening of Staff

Is there evidence the facility has provided education to staff on COVID-19 (e.g., symptoms, how it is transmitted, screening criteria, work exclusions)?

How does the facility convey updates on COVID-19 to all staff?

Is the facility screening all staff at the beginning of their shift for fever and signs/symptoms of illness? Is the facility actively taking their temperature and documenting absence of illness (or signs/symptoms of COVID-19)?

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

If staff develop symptoms at work (as stated above), does the facility:

- Inform the facility's infection preventionist and include information on individuals, equipment, and locations the person came in contact with; and
- Follow current guidance about returning to work (e.g., local health department, CDC: <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/hcp-return-work.html>).

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

7. Reporting to Residents, Representatives, and Families

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

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

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

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

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

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

- Yes No F884

9. Emergency Preparedness – Staffing in Emergencies

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

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

Yes No **E0024** N/A

10. Infection Preventionist (IP):

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

- Did 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?*
- Has the Infection Preventionist(s) completed specialized training in infection prevention and control?*
- Does the Infection Preventionist(s) participate in the quality assessment and assurance committee? The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.*

Note: If no to any of the question above, consider citing F882.

10. Is the facility in compliance with requirements set forth at 483.80(b)?

Yes No **F882**

11. Staff and Resident Testing

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?*
- 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?*

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- Did the facility's documentation demonstrate the facility conducted testing of residents and staff based on the identification of an individual diagnosed with COVID-19 in the facility in a manner that is consistent with current standards of practice for conducting COVID-19 tests?*
- 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.

11. Is the facility in compliance with requirements set forth at 483.80(h)?

Yes No **F886**