**COVID-19 Testing**

**Implementation Checklist**

**(05.26.2021)**

**Implementation Checklist: COVID-19 Testing**

| **Regulation** | **Suggested Actions** |
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| **F886 COVID-19 Testing**  “§ 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.”  (42CFR §483.80h)  Definitions:  “**Fully vaccinated**” refers to a person who is ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine.  **“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.”1 | * Review for comprehensive and updated Infection Prevention and Control policies that align with current federal, state, and local health department guidance including:   + COVID-19 testing for residents, staff, vendors/contractors and volunteers   + Determination of frequency of testing   + Testing Equipment Use (Manufacturer’s recommendations)   + Specimen Collection   + Personal Protective Equipment   + Cleaning and Disinfection   + Reporting processes     - CLIA     - NHSN     - State/Local Public Health     - Resident/Resident Representative   + Process for testing procurement and supply shortages   + Documentation processes     - Testing was completed and the results of each staff test     - Testing results     - Line List     - Medical record   + Testing refusal procedures     - Resident     - Staff     - Vendor     - Volunteer * Education:   + Testing Schedule   + Symptomatic   + Outbreak   + Testing Schedule     - Routine       * Vaccinated staff       * Unvaccinated       * staff   + Specimen Collection   + Use of Testing Device     - Cleaning and Disinfecting     - Calibration   + Reporting * Incorporate education into overall facility training plan * Audit employee training and in-service records for Testing related education and verification of competency * Monitor employee performance at varied times to observe compliance with facility policies and procedures (Process Surveillance) * Complete record review to determine that documentation of testing and reporting is consistent with policy and procedure * Identify current CLIA Waiver * Evaluate staff adherence to Present findings to QAPI Committee for discussion and follow up |
| **F884: COVID-19 Reporting to NHSN**  § 483.80 Infection control. (g) COVID-19 Reporting. The facility must— (1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to—  (i) Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;  (ii) Total deaths and COVID-19 deaths among residents and staff;  (iii) Personal protective equipment and hand hygiene supplies in the facility;  (iv) Ventilator capacity and supplies in the facility;  (v) Resident beds and census;  (vi) Access to COVID-19 testing while the resident is in the facility;  (vii) Staffing shortages; and  (viii) Other information specified by the Secretary.  (2) Provide the information specified in paragraph (g)(1) of this section at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention’s National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.  (3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—  (i) Not include personally identifiable information;  (ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and  (iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.  **Updates for F884:**  “42 CFR 483.80(g)(1)(viii)-(ix) requires LTC facilities report, on a weekly basis, the COVID-19 vaccination status of residents and staff, total numbers of residents and staff vaccinated, each dose of vaccine received, COVID-19 vaccination adverse events, and therapeutics administered to residents for treatment of COVID-19 through NHSN's LTCF COVID-19 Module.”2 | * Review and implement facility policy for reporting to NHSN including process to gather information related to:   + Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19   + Total deaths and COVID-19 deaths among residents and staff   + Personal protective equipment and hand hygiene supplies – inventory and availability   + Ventilator capacity and supplies in the facility   + Staff capacity   + Census * Identify position responsible for reporting and monitoring of related data. * Process to monitor QIES and NHSN systems for potential reporting errors and possible CMPs * Conduct process surveillance audit every 2 weeks to identify reporting is completed consistent with requirements * Evaluate staff adherence to Present findings to QAPI Committee for discussion and follow up * Review policy for notification/communication to resident, representatives and staff   + Notify by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other |
| **CLIA**  § 493.2 **Definitions.** (Modified): Condition level requirements means any of the requirements identified as “conditions” in § 493.41 and subparts G through Q of this part.  •§ 493.41 **Condition:** **Reporting of SARS-CoV-2 test results.** (New): During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a “SARS-CoV-2 test”) must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.  § 493.555(c) **Federal review of laboratory requirements.** (New): (c) The organization's or State's agreement with CMS that requires it to do the following: (6) Notify CMS within 10 days of any conditional level deficiency under §§ 493.41 or 493.1100(a).  § 493.1100 **Condition: Facility administration.** (New) (a) Reporting of SARS-CoV-2 test results. During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a “SARS-CoV-2 test”) must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.  § 493.1804 **General considerations.** (Modified) (c) Imposition of alternative sanctions. (1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions. (Except for a condition level deficiency under §§ 493.41 or 493.1100(a), CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not routinely inspected for compliance with condition-level requirements.)  § 493.1834 **Civil money penalty**. (New) (d)(2)(iii) For a condition level deficiency under §§ 493.41 or 493.1100(a), a CMP of $1,000 for the first day of noncompliance and $500 for each additional day of noncompliance. | * Identify current CLIA Waiver * Identify process for reporting * Review current reporting policy and process to align with federal, state and local health department requirements * Review competency process for POC Antigen testing units and reporting processes * Process surveillance audit to identify reporting consistent with requirements * Evaluate staff adherence to Present findings to QAPI Committee for discussion and follow up * Keeps certificate information current. Notify the State Agency of any changes in ownership, name, address or director within 30 days |
| **Routine Testing of Staff1**   * Community COVID-19 Activity Low (County positivity rate in the past week is <5%) – minimum testing frequency of unvaccinated staff is once a month * Community COVID-19 Activity Medium (County positivity rate in the past week is 5-10%) – minimum testing frequency of unvaccinated staff is once a week\* * Community COVID-19 Activity High (County positivity rate in the past week is >10%) – minimum testing frequency of unvaccinated staff is twice a week\*   \*Vaccinated staff do not need to be routinely tested.  \*This frequency presumes availability of POC testing on-site and the facility or where off-site testing turnaround time is <48 hours. | * Determine a process for review of county positivity rate (roles, responsibility, data source, accountability, documentation) |
| **Centers for Disease Control and Prevention “Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing, Updated Mar. 12, 2021:**  <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>  **“**Each point-of-care test has been authorized for use with certain specimen types and should only be used with those specimen types. Proper specimen collection and handling are critical for all COVID-19 testing, including those tests performed in point-of-care settings. A specimen that is not collected or handled correctly can lead to inaccurate or unreliable test results.”  **\*\*Risk Assessment Resource:**  <https://www.aphl.org/programs/preparedness/Documents>  /APHL%20Risk%20Assessment%20Best%  20Practices%20and%20Examples.pdf | * Perform a risk assessment before testing * Develop a system that includes:   + Follow manufacturer’s instructions for performing test   + Performs regular quality control and instrument calibration in accordance with the manufacturer’s instructions   + Follow proper manufacturer’s recommendations with use   + Follows infection prevention and control with testing   + Reads and records results   + Report all COVID-19 diagnostic and screening testing results     - Resident/Representative     - Physician     - CLIA     - NHSN |

**References and Resources**

1 Centers for Medicare & Medicaid Services: QSO-20-38-NH, 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 COVID19 Focused Survey Tool. August 26, 2020, Revised 04/27/2021: <https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf>

2Centers for Medicare & Medicaid Services: QSO-21-19-NH, Interim Final Rule – COVID-19 Vaccine Immunization Requirements for Residents and Staff, May 11, 2021: <https://www.cms.gov/files/document/qso-21-19-nh.pdf>

Centers for Disease Control and Prevention. Considerations for Interpreting Antigen Tests in Long-Term Care Facilities. January 15, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf>

Centers for Disease Control and Prevention. SARS-CoV-2 Antigen Testing in Long Term Care Facilities. Updated Jan. 7, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>

Centers for Disease Control and Prevention. Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing. Updated Feb. 26, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

Centers for Disease Control and Prevention. Interim Guidance for Antigen Testing for SARS-CoV-2. Updated May 13, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

Centers for Disease Control and Prevention. Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes. Updated Mar. 29, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html>

Centers for Disease Control and Prevention. Testing Guidelines for Nursing Homes. Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Personnel. Updated Jan. 7, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>

Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing. Updated Mar. 12, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

Centers for Disease Control and Prevention. COVID-19 Testing Overview. Updated Mar.17, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html>

Centers for Medicare & Medicaid Services. CMS Updates COVID-19 Testing Methodology for Nursing Homes. September 29, 2020: <https://www.cms.gov/newsroom/press-releases/cms-updates-covid-19-testing-methodology-nursing-homes>

Centers for Medicare & Medicaid Services: QSO-20-37-CLIA, NH, 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. August 26, 2020: <https://www.cms.gov/files/document/qso-20-37-clianh.pdf>

Centers for Medicare & Medicaid Services: QSO-20-29-NH. Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes. May 6, 2020: <https://www.cms.gov/files/document/qso-20-29-nh.pdf>

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