**COVID-19 Testing**

**Implementation Checklist**

**(12.05.2022)**

**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:  “**Close contact”** refers to someone who has been within 6 feet of a COVID-19 positive person for a cumulative total of 15 minutes or more over a 24-hour period.  **“Higher-risk exposure”** refers to exposure of an individual’s eyes, nose, or mouth to material potentially containing SARS-CoV-2, particularly if present in the room for an aerosol-generating 3 procedure. This can occur when staff do not wear adequate personal protective equipment during care or interaction with an individual.”1 | * Review for comprehensive and updated Infection Prevention and Control policies and procedures that align with current federal, state, and local health department guidance including:   + COVID-19 testing for residents, staff, vendors/contractors and volunteers for signs, symptoms or consistent with outbreak testing   + Routine testing is not generally recommended   + 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     - Testing results     - Line List     - Medical record   + Testing refusal procedures     - Resident     - Staff     - Vendor     - Volunteer * Education:   + Testing Schedule   + Symptomatic   + Outbreak   + 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.”2  (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.”2 | * Review and implement facility policy for reporting to NHSN including process to gather information related to:   + Resident Impact and Facility Capacity     - Admissions     - Newly Positive Tests     - Vaccination status     - Up-to-date Status     - Deaths     - Influenza     - Testing Availability     - Supplies and PPE Shortages   + Staff and Personnel Impact     - Newly Positive Tests     - COVID-19 Deaths     - Influenza     - Staffing Shortages   + Therapeutics     - In-house Stock     - Stock Stored Outside the LTCF * 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 education resources at: <https://www.cdc.gov/nhsn/ltc/covid19/index.html> |
| **F885 COVID-19 Reporting to Residents, Representatives and Families**  **“**(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.”2 | * Review policy and procedure 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 New and/or Modified CLIA Regulations for SARS-CoV-2 Test Results**  “§ 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.”3 | * 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 * **NOTE:**  Monitor for ALL updates and requirements related to the end of the Public Health Emergency in relation to reporting of COVID-19 testing |
| **Routine Testing**  **Routine testing of staff and residents is not generally recommended**  **Outbreak Testing: (two options)**   * Through contact tracing * Broad-based testing approach  1. Centers for Medicare & Medicaid Services. 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, Revised 09/23/2022: <https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf> 2. Centers for Disease Control and Prevention. Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic), Updated Sept. 23, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html> 3. Centers for Disease Control and Prevention. Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2, Updated Sept. 23, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html> 4. For specific questions, contact your local public health authority. | * Determine a process for outbreak testing * Provide education to all staff performing outbreak contact tracing |
| **Centers for Disease Control and Prevention “Guidance for SARS-CoV-2 Rapid Testing Performed in Point-of-Care Settings, Updated Apr. 4, 2022:**  <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.” | * 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. 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, Revised 09/23/2022: <https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf>

2 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>

3 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-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. Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic), Updated Sept. 23, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

Centers for Disease Control and Prevention. Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing. Updated July 15, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

Centers for Disease Control and Prevention. Guidance for Antigen Testing for SARS-CoV-2 for Healthcare Providers Testing Individuals in the Community. Updated Apr. 4, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

Centers for Disease Control and Prevention. Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2, Updated Sept. 23, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>

Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Rapid Testing Performed in Point-of-Care Settings. Updated Apr. 4, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

Centers for Disease Control and Prevention. COVID-19 Testing: What You Need to Know. Updated Sept. 28, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html>