



STATE OF WASHINGTON
DEPARTMENT OF SOCIAL AND HEALTH SERVICES
Aging and Long-Term Support Administration
PO Box 45600, Olympia, Washington 98504-5600

September 10, 2020

AL TSA: NH #2020-064
QSO-20-37-CLIA, NH AND QSO-20-38-NH REGARDING RULE CHANGES TO REQUIRE
COVID-19 TESTING AND GUIDANCE

Dear Nursing Facility/Home Administrator:

On August 3, 2020, RCS released an administrator letter ([#020-049](#)) informing you of two announcements made by the Department of Health and Human Services (HHS). On July 14, 2020, HHS announced ([press release](#)) an initiative to send rapid point-of-care (antigen based) testing instruments and tests to nursing homes. Building on the anticipated increased testing capacity, on July 22, 2020, HHS announced ([press release](#)) mandatory weekly testing for nursing home residents and staff under certain conditions.

The Centers for Medicare and Medicaid Services (CMS) provided more information about the required testing with [QSO-20-37-CLIA, NH](#) and [QSO-20-38-NH](#). CMS released both memos on August 26, 2020.

QSO-20-37-CLIA, NH

- 1) Long-Term Care (LTC) Enforcement requirements at 42 CFR part 488 have been revised to include requirements specific to the imposition of a Civil Money Penalty (CMP) for nursing homes that fail to report required COVID-19 related data to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) per §483.80(g)(1) and (2).
- 2) CMS published an interim final rule ([CMS-3401-IFC](#)) on August 25, 2020, that includes new requirements at 42 CFR §483.80(h) for nursing homes to test all staff for COVID-19 and to offer a COVID-19 test to residents as specified by the HHS Secretary. Guidance from the Secretary about when and how often to perform the testing is found in QSO-20-38-NH. The rule became effective September 2, 2020.
- 3) The CMS-3401-IFC interim final rule also updated CLIA (Clinical Laboratory Improvement Amendments) regulations to require all laboratories to report SARS-CoV-2 (COVID-19) test results in a standardized format and at a frequency specified by the HHS Secretary for the duration of the public health emergency. **The rule was effective September 2, 2020, but CMS provided a three-week grace period for the reporting requirement. Health care facilities using point-of-care COVID-19 testing devices under a CLIA Certificate of Waiver, including nursing homes, are required to report test results under this CLIA regulation. Facilities contracting with a laboratory instead of performing tests themselves are not responsible for reporting; the laboratory must complete the reporting.**
 - a) Under the new regulation, specific data elements are required to be reported daily. According to the guidance, reporting can be done to the state Department of Health (DOH) or local health jurisdiction, or a reporting platform. The reporting mechanisms have not been sufficiently developed to accept reporting.
 - i) Until the reporting mechanisms are in place, Residential Care Services (RCS) and DOH recommend keeping a log of all testing that includes the required elements, beginning September 2, 2020. Keeping a log or spreadsheet will document your

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- effort to report, and enable you to report when the reporting mechanism is operational.
- ii) For more information on the reporting requirements, including the required elements and the formatting of the report, please review the following links:
 - (A) [HHS Lab Data Reporting Guidance](#)
 - (B) [CDC website for reporting guidance](#)
 - b) Once reporting mechanisms are in place, failure to report COVID-19 test results will result in a condition level violation of the CLIA regulation and may result in the imposition of a CMP. The CMP will be \$1,000 for the first day of noncompliance and \$500 for each subsequent day of noncompliance.
 - c) CLIA, not RCS, will review and regulate the reporting requirement. However, Washington state has “exempt” status with CLIA and CMS, which means our state has enacted laws relating to the laboratory requirements that are equal to or more stringent than CLIA/CMS requirements. Under the exempt status, the state laboratory licensure program, which resides with DOH, is approved to conduct oversight of laboratory programs instead of CLIA. Therefore, DOH will be responsible to monitor the new reporting requirements, and will issue citations and enforcement penalties if needed.

QSO-20-38-NH

QSO-20-38-NH provides guidance on the new rule published in CMS-3401-IFC that requires nursing homes to test staff, and offer testing to residents under certain conditions. The new rule modified 42 CFR §483.80 and added §483.80(h), which will be cited at F886. The rule requires COVID-19 testing, completed in accordance with current standards of practice. Additionally, the rule requires:

- Documentation of the testing;
- Action to prevent transmission upon identification of an individual with symptoms or who tests positive;
- A procedure to address residents or staff who refuse or are unable to be tested; and
- Contacting the DOH and local health jurisdiction to assist with testing and testing supplies if the facility cannot complete the testing.

Guidance for F886

Please read the QSO memo for detailed information. Highlights of the guidance are:

- Testing of staff and residents
 - Testing can be done through the point-of-care testing, or through arrangement with an offsite laboratory.
 - Facility staff include direct employees and those working under arrangement (consultants, contractors, volunteers, students, etc.). If the facility arrangement is to have the contractor provide the testing, the facility is responsible to have the documentation of the testing, which must meet the timeframes of the facility’s testing frequency.
 - When prioritizing individuals to be tested, prioritize individuals with symptoms of COVID-19 first, then testing triggered by an outbreak, then routine testing.
- Testing of staff and residents with COVID-19 symptoms
 - Facilities must test staff with symptoms and are expected to restrict those staff from the facility pending the test results. Test results determine next steps.
 - Residents with COVID-19 symptoms must be tested and placed on transmission-based precautions pending the test results.
- Testing of staff and residents in response to an outbreak.

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- Upon identification of a single new case of COVID-19 (an outbreak), all staff and residents should be tested, and all individuals who tested negative should be retested every three to seven days until testing reveals no new cases among residents and staff for a period of at least 14 days since the most recent positive result.
- For individuals who test positive, repeat testing is not recommended.
- Routine testing of staff.
 - 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 are available on the following website (see section titled “COVID-19 Testing”): <https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg>. For tests done more frequently than monthly, the frequency presumes availability of a test with a turnaround time of less than 48 hours.
 - If the county positivity rate is less than 5%, testing frequency is once a month.
 - If the county rate is 5% to 10%, testing frequency is once a week.
 - If the county rate is greater than 10%, testing frequency is twice a week.
 - If 48-hour turnaround times cannot be met due to testing supply shortages or other reasons, the facility should document efforts to obtain quick turnaround test results.
 - Facilities should monitor their county positivity rate every other week and adjust the frequency to meet the above guidelines.
 - If the county positivity rate increases to a higher level of activity, the facility should begin testing staff at the increased frequency as soon as the criteria is met.
 - If the county positivity rate decreases to a lower level of activity, the facility should continue testing staff at the higher frequency for at least two weeks before reducing testing frequency.
 - The above testing frequency is the minimum testing standard. Facilities may consider other factors and decide to test more frequently. DOH and local health officials may also direct more frequent testing.
 - Routine testing of asymptomatic residents is not recommended unless prompted by a change in circumstance, such as those who leave the facility regularly.
- Refusal of testing
 - Facilities must have procedures in place to address staff who refuse testing. Procedures should ensure 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. Procedures must ensure that if a resident with symptoms of COVID-19 refuses testing, the resident is placed on transmission-based precautions.
- Other testing considerations
 - Individuals who have recovered from COVID-19 and are asymptomatic do not need to be re-tested for COVID-19 for three months. Testing should be encouraged again three months after the date of symptom onset with the prior infection.
 - While not required, facilities may test visitors to help facilitate visitation. This testing should not be prioritized over staff and resident testing.
- Conducting testing

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- The facility must obtain an order from a physician, physician assistant, nurse practitioner, or clinical nurse specialist in accordance with Washington State law before testing a resident. This may be accomplished with physician approved policies (e.g., standing orders), or other means as specified by scope of practice laws and facility policy.
- Rapid point-of-care testing devices are prescription use tests and an order from a qualified healthcare professional must be obtained for their use.
- Testing must be conducted according to nationally recognized standards of practice.
- The test must be a molecular test or an antigen test. An antibody test for COVID-19 does not meet the requirements under this regulation.
- A current CLIA certificate of waiver must be maintained that supports the level of testing done at the facility.
- Documentation of Testing
 - Facilities must maintain documentation to demonstrate compliance with the testing regulations.
 - Specific guidance is in the QSO memo regarding documentation for symptomatic individuals, documentation during an outbreak, and documentation of routine testing of staff.
 - The facility must have a documented procedure to address testing refusals.
 - If the facility is unable to test as required, the facility must document attempts to procure testing, and contacts made to DOH and the local health jurisdiction for assistance.
- Surveying for compliance
 - DOH surveyors will assess required laboratory reporting.
 - RCS surveyors will use the “COVID-19 Focused Survey for Nursing Homes” pathway to assess compliance with the testing regulations.
 - The COVID-19 Focused Survey for Nursing Home document has been revised and is attached to QSO-20-35-NH.
 - Documentation of testing and symptom surveillance will be reviewed, including reviewing a sample of resident and staff records.
 - Observation of testing will be conducted, if possible,
 - Surveyors will review documentation of attempts to obtain testing supplies and to complete testing, including contacting DOH and the local health jurisdiction for assistance, if testing is not done as required.

These changes are effective immediately. The new rules became effective September 2, 2020.

For questions related to the nursing home testing requirement, contact:

DNH_TriageTeam@cms.hhs.gov.

Thank you for your continued commitment to resident health and safety. If you have any questions, please contact Lisa Herke, Nursing Home Policy Program Manager at (509) 209-3088 or lisa.herke@dshs.wa.gov.

Sincerely,

Candace Goehring

Candace Goehring, Director
Residential Care Services

DSHS: “Transforming Lives