CMS Testing Requirement Summary

September 1, 2020

LTC Testing Requirements

Interim Final Rule with comment period will be published and effective on September 2. The Interim Rule establishes requirement to Report COVID-19 Test Results During the Public Health Emergency but best to turn to QSO-20-38-NH for the specific guidance.

QSO Memo includes Guidance to meet new testing requirements and revises the Focused Infection Control Survey tool to incorporate these new requirements as well as the requirement to have a designated infection preventionist and other COVID-19 guidance updates. (New portions of survey italicized.)

The new testing requirements of 483.80(h) will be cited under new tag F886.

Nursing homes may meet testing requirements through the use of point-of-care testing devices or through off-site laboratory testing. Only antigen tests and nucleic acid tests are acceptable; antibody tests will not meet requirements. Tests that are processed at an off-site laboratory must return results within 48 hours.

Definition of Staff

Staff are considered any individuals who are employed by the nursing home, who volunteer for the nursing home, or who provide services as part of an arrangement with the nursing home. This could include hospice workers, caregivers, or students participating in a nurse aide training and competency evaluation program. If staff receive testing off-site, such as contracted staff receiving testing through their employer, the nursing home must obtain documentation to verify that testing requirements have been met. Residents' visitors are not included in this definition.

Test Order Requirement

Recall that a nursing home 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, for COVID-19 testing. This may be accomplished through the use of physician-approved policies, such as standing orders, or other means as specified by scope of practice laws and individual nursing home policy.

Trigger Testing

Symptomatic: Nursing homes must now test all staff and residents who show symptoms consistent with COVID-19

Outbreak: Nursing homes must initiate outbreak testing procedures in response to one new confirmed case among staff or one new confirmed nursing home-onset case among residents. During outbreak testing, all residents and staff must receive an initial test. Nursing homes must implement appropriate response for all who test positive, including cohorting and implementing

transmission-based precautions for residents, including those who are asymptomatic and tested positive, and restriction from work for staff, including staff who are asymptomatic and tested positive. Nursing homes must continue testing all residents and staff who test negative every 3-7 days until 14 days have passed since the last positive test result.

Routine Staff Testing

Nursing homes must conduct routine testing of all staff according to community prevalence. ***In order to determine testing based on community prevalence, nursing homes must monitor the nursing home site at data.cms.gov every other week for the positivity rate of the county in which the nursing home is located.***

If the county positivity rate increases, the nursing home must immediately increase testing for the appropriate frequency. If the positivity rate for the county decreases, the lower positivity rate must be sustained for a period of 2 weeks before the nursing home can reduce testing to the appropriate frequency. The county positivity rate will determine the frequency of routine staff testing as follows:

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 turn-around time is < 48 hours.

The testing frequency outlined above represents minimum testing requirements. Nursing homes may choose to increase routine testing frequency based on other factors including state or local mandates, community prevalence in neighboring counties, or community prevalence in a county or counties where a significant portion of staff live.

Staff and Resident Refusals of Testing

Nursing homes must have a plan for residents and staff who refuse testing or are unable to be tested. For symptomatic residents who decline testing or asymptomatic residents who decline testing during an outbreak, the nursing home should use a person-centered approach to address concerns and questions, provide education, and discuss potential alternatives, such as alternative specimen collection methods. If the resident continues to decline testing, the nursing home should do the following:

- For symptomatic residents, implement transmission-based precautions until the resident meets criteria for **discontinuation of transmission-based precautions**.
- For asymptomatic residents, the nursing home should exercise extreme vigilance, such as through additional monitoring, to ensure the resident maintains distance from other

residents, wears a face covering, and practices effective hand hygiene until outbreak testing is complete.

The nursing home should address staff who refuse testing as follows:

- For symptomatic staff, restrict the staff member from work until he/she meets **return-to-work criteria**.
- For asymptomatic staff who refuse testing during an outbreak, restrict the staff member from work until outbreak testing is complete.
- For asymptomatic staff who refuse routine testing, refer to occupational health and local jurisdiction policies.

Procedures for When Requirements Cannot Be Met

Nursing homes that are unable to meet testing requirements due to emergency situations, such as community testing supply shortages, limited access, or inability of laboratories to process test results within 48 hours, must contact the state/local health department for assistance.

Other Testing Considerations

Consistent with **CDC recommendations**, nursing homes are not required to re-test asymptomatic individuals who have recovered from COVID-19 within the past 3 months. Testing should resume as required 3 months after symptom onset of the initial illness. In other words, an individual who first showed symptoms on June 1 and was confirmed positive for COVID-19 does not need to be re-tested until after September 1, provided the individual remains asymptomatic.

Nursing homes should continue screening for fever and symptoms all residents, staff, and any visitors who may enter the nursing home, despite any ongoing testing. Nursing homes should refer regularly to the **CDC guidance** for the most up-to-date list of COVID-19 symptoms.

PPE Use for Testing

For providers collecting specimens or within 6 feet of patients suspected to be infected with SARS-CoV-2, 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.

Follow Standard Precautions when handling clinical specimens, including hand hygiene and the use of PPE, such as laboratory coats or gowns, gloves, and eye protection. If needed, additional precautions can be used, such as a surgical mask or face shield, or other physical barriers, such as a splash shield to work behind.

Change gloves after adding patient specimens to the instrument.

Training

Training on the Use of Devices Training for the use of the point-of-care devices is available online at the corresponding brand's special nursing home concierge site. For Quidel Sofia and Sofia 2 machines: https://togetheragain.quidel.com/. For BD Veritor machines: https://www.bdveritor.com/long-term-care-facilities/system-overview/.

Testing Documentation Requirements

All testing must be documented. For residents, testing must be documented in the resident's medical record. Staff testing must be documented in the personnel file. All documented test results must be maintained according to standards for personal health information (PHI). Documentation should include the following information:

- For testing of symptomatic residents/staff: date and time of symptom onset, when the resident/staff was tested, the result of the test, and actions taken.
- For testing of asymptomatic residents/staff in response to an outbreak: date the triggering case was identified, date all residents and staff were tested, dates of subsequent retests, and results of all tests.
- For routine testing of staff: applicable county positivity rate, corresponding test frequency, date the positivity rate was collected, date of rests conducted, and results.
- For any resident/staff who refuse or are unable to participate in testing: document the nursing home's policy on refusals, any residents/staff who refuse or are unable to be tested, and how those issues were addressed.

Test Result Reporting

Recall that nursing homes must report all tests conducted in the nursing home using a point-of-care testing device according to **Clinical Laboratory Improvement Amendments (CLIA) requirements**. ***This includes reporting all tests within 24 hours to the state or local health department. Nursing homes that fail to comply with CLIA reporting requirements will be imposed a Civil Money Penalty (CMP) of $1,000 for the first day of non-compliance and $500 for each additional day of non-compliance up to $10,000.***

Nursing homes must also continue reporting COVID-19 data directly to CDC through the National Healthcare Safety Network (NHSN) system on a weekly basis. Nursing homes that fail to comply with NHSN reporting requirements will be imposed a CMP of $1,000 for each week of non-compliance, with an incremental increase of $500 per week of noncompliance. So, for example, failure to report for one week will result in a $1,000 CMP. Failure to report for a second week will result in a CMP of $1,500, and a CMP of $2,000 for the third week, up to $6,500.

Lastly, nursing homes must report all positive COVID-19 test results to the state/local entity for contact tracing. Additional details covered in **QSO Memo 20-37-CLIA,NH**.

IDPH Antigen POC Testing Guidance

IDPH released POC Testing Guidance on August 24 before CMS's rule. Much of the CMS rule invalidates the IDPH guidance, but here are some items that LAI believe are still valid:

- To perform test, must have CLIA certificate of waiver. Contact SHL at 319-335-4500 with questions.
- All staff testing must read the package insert and document that they have done so. The procedure detailed in the insert must be followed exactly and safety guidance should be followed. (LAI recommends documenting additional video training that staff may be doing about the system through the manufacturer's web site.)
- Reports of both positive and negative test results are required. IDPH will contact facilities with a mechanism to electronically report all tests performed.

- A biosafety risk assessment must be performed before testing is performed. Use appropriate PPE to perform the test. Clean and disinfect the area around the instrument after each test.
- If a negative test result is received for a resident or staff member for whom COVID infection is highly suspected, IDPH and SHL recommend conducting a confirmatory diagnostic PCR test.
- Additionally Q&As 4-8 in the document are valid related to operations and reimbursement.

FDA Guidance on Antigen Testing (8/24) **FAQ**

"[W]hen screening asymptomatic individuals, health care providers should consider using a highly sensitive test, especially if rapid turnaround times are available. If highly sensitive tests are not feasible, or if turnaround times are prolonged, health care providers may consider use of less sensitive point-of-care tests, even if they are not specifically authorized for this indication (commonly referred to as "off-label"). **For congregate care settings, like nursing homes or similar settings, repeated use of rapid point-of-care testing may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround times**.

If less sensitive tests, such as some rapid point-of-care tests, are used, health care providers should be aware of the performance of the tests and may want to consider different testing approaches, such as serial testing. **"Negative" results should be considered as "presumptive negative," and health care providers should consider them in the context of clinical observations, patient history, and epidemiological information.** Thus, if there is a significant new outbreak in a congregate care facility or high clinical suspicion of an infection in an individual resident, a negative point-of-care test should be confirmed with a highly sensitive molecular test (refer to CDC guidelines). **It is not necessary to perform confirmatory high-sensitivity molecular tests on individuals with negative antigen test or other point-of-care test results if they are obtained during routine screening or surveillance."**

Member FAQs:

Q1: Do the testing requirements in the Interim Final Rule and the QSO Memo 20-38-NH apply to Assisted Living Programs and other aging services providers?

A1: No, the rule and memo apply to Medicare and/or Medicaid certified LTC providers who are required to follow the Medicare Conditions of Participation for LTC. The POC testing devices are being sent to LTC providers with CLIA waivers.

Q2: Is the POC Antigen testing device only for symptomatic people?

A2: The FDA released an FAQ on 8/24 which stated that for "congregate care settings, like nursing homes or similar settings, repeated use of rapid point-of-care testing may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround times".

Q3: Is it necessary to confirm negative test results?

A3: For symptomatic testing, “negative” results should be considered as “presumptive negative,” and health care providers should consider them in the context of clinical observations, patient history, and epidemiological information. **For baseline testing**, it is not necessary to perform confirmatory high-sensitivity molecular tests on individuals with negative antigen test or other point-of-care test results if they are obtained during routine screening or surveillance. For outbreak testing**,** nursing homes must continue testing all residents and staff who test negative every 3-7 days until 14 days have passed since the last positive test result (a POC test meets this requirement).

Q4: We haven’t received our POC device and don’t have a lab that can meet the 48 hours requirement?

A4: If a LTC provider has documentation that demonstrates their attempts to perform and/or obtain testing in accordance with these guidelines (timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours), surveyors should not cite the LTC provider for noncompliance (page 10 of QSO 20-38-NH).

Q5: Do I test asymptomatic residents?

A5: Asymptomatic residents would only be tested during “outbreak testing” protocol if there is a positive staff member or a positive resident with nursing home onset. Asymptomatic residents are not included in the Routine Testing protocol, only staff.

Q6: Where do I find the county positivity rate?

A6: CMS will post the data in a zip file on this website: https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg. Look under the COVID-19 Testing heading in the text, the link for the zip file is indicated as the second “here” in the paragraph.

Q7: If I believe my county positivity rate is currently higher than the CMS data shows, would I test according to the CMS data or the current rate?

A7: CMS states that the requirements outlined in QSO 20-38-NH are the minimum expectations. Providers may consider other factors and test at a frequency that is higher than required.

Q8: When does testing requirements start?

A8: The rule is effective September 2. DIA will distribute the QSO memorandum to survey team by September 2, but they do not anticipate using the revised Focused Infection Control Survey until September 8. Providers should be taking deliberate document steps towards compliance with the rule. Members should know which device they will receive and should begin training staff. If a device is not expected for some time, members should be documenting attempts to make other arrangements with another lab. Note that the CLIA requirements for 24-hour reporting of lab test results is currently effective.

Q9: Where do I report test results to IDPH?

A9: IDPH will be establishing an electronic reporting system by mid-September and sharing with providers. Before then, IDPH will distribute an excel template that meets the reporting requirements. Providers need to submit to IDPH using Secure messaging to comply with HIPAA.

Q10: Can IDPH change the CMS requirements?

A10: IDPH can make the guidance more restrictive, not less restrictive since the federal government has acted. IDPH can assist with interpretation on questions not addressed by CMS and the local reporting process for results.

Q11: Does IDPH want all positive/negative test results or just the POC results?

A11: Each laboratory is responsible for reporting results to IDPH. LTC Providers will only report POC test results since they are the laboratory in that instance under the CLIA waiver. Both positive and negative from the POC tests completed onsite should be reported.

Q12: We have a CLIA waiver, but I am not sure what device or when it is scheduled to arrive, who do I contact?

A12: Please contact Shannon Strickler or Rebecca Siglin at LAI.

Q13: When they say an outbreak, can the testing be limited to the area/neighborhood indicated through contact tracing?

A13: LAI does not interpret the QSO memo to allow that but will inquire with IDPH/DIA.

Q14: Does 1 staff positive requiring outbreak testing mean that I need to move back to phase 1 of the reopening guidance?

QA14: No, the reopening guidance has its own definition (3 or more) which is separate from the testing guidance.

Q15: *Do we need to test residents' visitors for compassionate care and/or end of life?*

A15: 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.

Q16: What is the role of the state hygienic laboratory (SHL)?

A16: Unless a different announcement is made, providers should not anticipate any changes to the role that the SHL currently play in testing today. The reopening guidance includes

information on the SHL role for testing which remains current. CMS stated this afternoon that a blanket notice from the SHL will not be enough to document efforts to secure testing supplies or alternatives.

Q17: Will this start a new round of Focused Infection Control Surveys for all LTC providers?

A17: The release of a new focused infection control survey tool will NOT launch a new round of infection control surveys of all LTC providers in the state. Rather, the tool will be substituted for the old one when it would have been used such as the focused infection control survey within 3-5 days of an outbreak, 20 percent of recertification survey, or when onsite for another reason. DIA anticipates implementing the new tool on Tuesday, September 8.

Q18: How should campus-based priorities decide who to test?

A18: The testing requirements apply to the Medicare/Medicaid Certified LTC provider staff which would include front-line staff, administrative staff, and ancillary departments. DIA shared that testing should be prioritized for individuals with direct contact with resident or with staff who have direct resident contact. This prioritization related to resident and staff contact also applies to volunteers and contractors.

Q19: Do PRN/seasonal workers need to be tested?

A19: PRN and seasonal works should be tested if scheduled.

Q20: How should testing be prioritized?

A20: CMS shared with DIA on August 31 that testing should be prioritized as symptomatic residents/staff, outbreaks, and routine testing (in that order). They did not address the question of prioritization of ancillary staff.

Q21: What will DIA be looking for in the early days of implementation?

A21: In the near term, DIA will be looking to ensure that providers demonstrate knowledge of the QSO-20-38-NH memo and its requirements, have knowledge of what is required, and have documented efforts to comply if unable to do so. DIA will distribute information to surveyors on the memo this week and ensure they are aware of the information on page 5 regarding good faith compliance efforts related to presence of supplies and lab availability.

Q22: How do I decide whether a follow-up PCR test should be conducted to confirm a negative antigen test result.

A22: Confirming negative point-of-care antigen test results with a PCR test may be recommended under certain circumstances but is not necessary for all circumstances. The decision to perform confirmatory PCR testing should be determined based on clinical context such as symptom presentation and disease prevalence. This means that if the individual is

showing symptoms or has been exposed to someone who is COVID-positive and the antigen test result is negative, a PCR test may need to be performed. If the individual is asymptomatic and there is no known exposure, a PCR test may not be necessary. CDC has created this tool to help guide decisions about when to conduct follow-up PCR testing.