FAQ of CMS Interim Final Rule on Nursing Home Staff Testing Requirements

1. What is the effective date of these new regulations?

Effective date: The regulations are effective immediately upon their publication at the Office of the Federal Register, which has not occurred yet.

2. Are LTC staff required to be tested for COVID-19 under the new regulations?

Yes, CMS is amending the current infection control requirements for LTC facilities at § 483.80 by adding a paragraph (h) that requires a facility to test all of its residents and facility staff for COVID-19.

3. What is the definition of staff at an LTC facility?

Under this requirement, "staff" are considered any individuals employed by the facility, any individuals that have arrangements to provide services for the facility, and any individuals volunteering at the facility.

CMS expects that only those individuals that are physically working on-site at the facility be required to be tested for COVID-19. The facility may have staff, including individuals providing services under arrangement and volunteers, who provide services for the facility from an off-site location that is not physically located within the facility, and such staff would not be required to be tested for COVID-19.

4. Did CMS establish a specific criteria or frequency for COVID-19 testing?

At this point, CMS did not establish a specific criteria or frequency for COVID-19 testing.

5. What is now required of LTC's under § 483.80(h)

CMS is requiring that resident and staff testing for COVID-19 be conducted based on parameters set forth by the Secretary. These parameters may include, but are not limited to:

- Testing frequency;
- The identification of any facility resident or staff diagnosed with COVID-19 in the facility;
- The identification of any facility resident or staff with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;
- The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;
- The response time for test results; and
- Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

6. In what manner must the LTC residents and staff be tested for COVID-19?

CMS is requiring that all resident and staff testing be conducted in a manner that is consistent with current professional standards of practice for conducting COVID-19 tests. Current "professional standards of practice" refers to those professional standards that apply at the time that the care or service is delivered.

7. How must the LTC document their testing methods?

All completed tests and results must be documented in staff and resident records, as well as documentation for volunteers or contract personnel. CMS is requiring that for each instance of resident or staff COVID-19 testing, the facility document that testing was completed and the results of each staff test. CMS expects that this documentation would be located in the staff personnel record for all staff.

Consistent with the documentation requirements CMS is adding for LTC facility staff, CMS is requiring that the facility document in the resident's medical record that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

8. What are the reporting requirements for LTC's under the new regulations?

In accordance with the current regulatory requirements for LTC facilities at § 483.80(g), facilities are required to electronically report information about COVID-19 in a standardized format specified by the Secretary, which includes reporting suspected and confirmed COVID-19 infections among residents and staff.

For facility residents who present with symptoms consistent with COVID-19 or who test positive for COVID-19, CMS expects the facility to take measures to mitigate the transmission of the virus within the facility that may include resident cohorting, consistent with CDC's guidance.

9. What is the proper protocol to follow if a staff member refuses to be tested for COVID-19?

CMS is requiring that the facility have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse or are unable to be tested.

In this instance, CMS also expects facilities to take steps to maintain the health and safety of its staff and residents who have not been diagnosed with COVID-19 that may include limiting the staff's access to the facility and cohorting residents.

10. What is the proper protocol if the LTC facility does not have adequate COVID-19 testing supplies?

CMS is requiring at § 483.80(h)(6) that the LTC facility must coordinate with state and local health departments on the availability of testing supplies, obtaining testing supplies, and processing test results when necessary.

Facilities may also coordinate with their local certified laboratories covered under Clinical Laboratory Improvement Amendments (CLIA) on the availability of testing supplies, obtaining testing suppliers, and processing test results.

Considerations such as access to adequate testing supplies and arrangements for acquiring testing supplies must be addressed by a facility's infection prevention and control plan. Additionally, the testing plan must include any arrangements that may be necessary to conduct, process, and receive test results prior to the administration of the required tests.

11. How should a lab or an LTC handle processing COVID-19 testing results?

Supply availability and processing of results should be coordinated with state and local health departments or local laboratories. Considerations such as access to adequate testing supplies and arrangements for acquiring testing supplies must be addressed by a facility's infection prevention and control plan. Additionally, the testing plan must include any arrangements that may be necessary to conduct, process, and receive test results prior to the administration of the required tests.

12. What is the proper protocol for handling staffing shortages at an LTC?

CMS states that facilities must: Maintain appropriate staffing levels to provide a safe work environment for healthcare personnel (HCP) and safe resident care and assess their staffing needs and the minimum number of staff needed to provide a safe work environment and care for residents, their ability to accommodate or replace staff who are unable to work.

13. Where should the COVID-19 test results/data be sent?

This new regulation requires nursing homes to report COVID-19 related facility data to the CDC National Healthcare Safety Network ("NHSN"). These new CMS reporting requirements do not preclude a facility from following all state and local public health reporting laws and regulations.

CMS revised the requirements to require facilities to electronically report information about COVID-19 in a standardized format and at a frequency specified by the Secretary, but not less than weekly to the CDC NHSN. With this Interim Final Rule ("IFC"), CMS is furthering its enforcement efforts that facilities report COVID-19 related information to the CDC's NHSN.

14. Is an order from a physician or other practitioner required before conducting a COVID-19 test?

CMS is revising the previous policy outlined in the May 8th COVID-19 IFC, which allowed for broad COVID-19 testing for a single beneficiary without a physician order, by establishing that, only a single COVID-19 test without a treating physician order, is reasonable and necessary.

After the first COVID-19 test, a treating physician order is required to conduct an additional COVID-19 test, for Medicare payment purposes

15. Would an order from a pharmacist, and not a physician, suffice?

Yes, CMS is also establishing a policy whereby tests can be covered when ordered by a pharmacist or other healthcare professional who is authorized to order diagnostic laboratory tests, in accordance with state scope of practice and other pertinent laws.

16. When does this limitation on COVID-19 tests go into effect?

This limitation on tests without a physician/other practitioner order will apply beginning on the effective date of this rule, and any tests furnished prior to the effective date will not be considered for purposes of this limit on tests without a physician or other practitioner order.

In other words, if a beneficiary received a test or multiple tests without an order before the effective date of this rule, these tests would not count toward the limit of one test without a physician or other practitioner order under this rule.

17. What are the requirements for laboratories after it receives COVID-19 test results?

Nursing homes that perform point-of-care ("POC") testing are considered laboratories under the rule and will be required to report the results from each such test, in such form, manner, and frequency prescribed by CMS.

18. What are the benefits of point-of-care ("POC) testing?

This method of testing effectively reduces the cost-per-test from approximately $100 to only $20. These efforts to provide every facility with these devices continue, but for the purposes of CMS estimates, CMS assumes a cost of $60 per test; this accounts for the potential cost of replacing the antigen testing device, as well as the possibility that some facilities will choose to verify negative results with lab testing. The cost of these testing activities will ultimately depend on the extent of future outbreaks, and how the best practices, and thus CMS' parameters for universal testing, evolve.

19. Which laboratories or LTC's will be most affected by the new regulations and reporting requirements?

While reporting of SARS-CoV-2 test results affects all laboratories performing this testing, CMS believes that meeting the new reporting requirements will be more challenging for point-of-care laboratories given that this requirement creates the need for systemic changes to the ability to report results.

If a laboratory does not currently have this capability to report in the form and manner specified by the Secretary, they would need to expeditiously ensure that the laboratory was able to submit the SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

20. What are some additional requirements of laboratories during the COVID-19 PHE?

Facilities performing point-of-care testing will be required to report on testing in the timeframes and using the format required by CMS.

Failure to report timely and accurately can result in CMPs calculated on a daily basis starting at $1000 for the first day and $500 for every subsequent day of noncompliance. Amount should not exceed $10,000 per episode of noncompliance. An episode is defined as per sample not reported.

21. What happens if the laboratory/facility fails to submit the COVID-19 test results to the Secretary?

Failure to submit COVID-19 test results to the Secretary will be considered a violation, resulting in condition level deficiencies for which Civil Money Penalties ("CMPs") may apply.

22. What are the CMPs that can be levied against the laboratories/facilities?

In § 493.1834, CMS is amending the provision by adding paragraph (d)(2)(iii) to define the per day CMP amounts that may be imposed as a result of SARS-CoV-2 reporting violations.

- Such CMPs will be $1000 for the first day of noncompliance with the new reporting requirements, and $500 for each subsequent day the laboratory fails to report SARS-CoV-2 test results.
- The statute allows for the imposition of CMPs in an amount not to exceed $10,000 for each violation (for example, per sample not reported) or for each day of substantial noncompliance.
- CMS believes imposing CMPs based on a per day basis is a fairer and more effective penalty for failure to report than a per violation basis. The latter could lead to large CMPs for brief lapses in reporting.