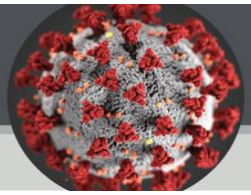

CMS COVID-19 Testing Requirements for Nursing Homes:
FREQUENTLY ASKED QUESTIONS
Revised: Sept. 10, 2020

CMS has issued a new rule requiring nursing homes to test staff and residents for COVID-19. The rule also requires laboratories conducting COVID-19 testing – including nursing homes that conduct point-of-care antigen testing – to report patient-level results of those tests on a daily basis. Facilities should review these CMS memos that give detailed guidance about implementation of these requirements: QSO-20-38-NH: Facility Testing Requirements and Revised COVID-19 Focused Survey Tool, and QSO-20-37-CLIA,NH: Requirements for Reporting of SARS-CoV-2 Test Results by (CLIA) Laboratories

This resource provides answers to common questions about the new requirements and reflects our current understanding as of the revision date above. There are many issues where we are still seeking guidance on your behalf, and we will revise and expand this document as we obtain more information.

General Questions

When is the rule effective?
The rule took effect on 09/02/2020.

Does the CMS rule apply to assisted living?
No. The rule applies only to federally-certified nursing homes.

Survey & Enforcement

Will the MN Department of Health begin enforcing the rule immediately after the Sept. 2? Can facilities expect enforcement without lead time?
Facilities must assume MDH may issue citations at any time after the effective date and should begin implementation of the requirements immediately. MDH has not indicated that lead time or a grace period will be provided.

What do we do if we are struggling to meet the testing timelines? Will we be cited? (Updated)
CMS memo QSO-20-38 states: If the 48-hour turn-around time cannot be met due to community testing supply shortages, limited access or inability of laboratories to process tests within 48 hours, the facility should have documentation of its efforts to obtain quick turnaround test results with the identified laboratory or laboratories and contact with the local and state health departments.

The memo also states clearly that, if a facility has documentation that demonstrates its attempts to perform and/or obtain testing in accordance with these guidelines (e.g., timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours), surveyors should not cite the facility for noncompliance.

CMS and MDH understand that testing capacity will vary from time to time and from place to place, and that facilities may not have the resources to do all of the required testing – especially in the early days of implementing the rule, when significant numbers of facilities are working to establish connections with labs for testing of staff.

Facilities are expected to make persistent, good faith efforts to meet the new requirements, to prioritize testing if they are unable to complete all that the rule requires, and to document your efforts thoroughly. With respect to efforts to secure an arrangement with a lab that can timely process tests, for example, facilities should document persistent attempts, including dates, times and the people you have communicated with. As another example, once lab arrangements are in place, facilities should carefully document the collection of specimens and record the date/time at which the specimens were delivered to the lab.

If you are struggling to secure a lab connection, or to complete testing on the frequency that applies to your facility, submit a request for help to the SEOC through REDCap. MDH still has capacity to send a specimen collection team out if you need it, even if you have had a state team out before, and can help with making those lab connections too.

TESTING OF FACILITY STAFF

Who is included in Facility Staff? **(New)**

"Facility staff" includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions. For the purpose of testing "individuals providing services under arrangement and volunteers," facilities should prioritize those individuals who are regularly in the facility (e.g., weekly) and have contact with residents or staff. We note that the facility may have a provision under its arrangement with a vendor or volunteer that requires them to be tested from another source (e.g., their employer or on their own). However, the facility is still required to obtain documentation that the required testing was completed during the timeframe that corresponds to the facility's testing frequency, as described in Table 2 below.

Does facility staff include only direct care staff or all staff? For example, would the CFO or HR director need to be tested?

The definition of facility staff in QSO 20-38-NH does not limit the requirement to direct care staff, so at this time we read the rule to require testing of all staff, regardless of position.

If a staff person works exclusively from a remote office or from home and does not enter the facility, does s/he have to be tested?

The definition of facility staff in QSO 20-38-NH does not identify an exception for employees who work offsite, so at this time we read the rule to include all staff.

Are we required to test Essential Caregivers? **(Updated)**

We don't know yet if the CMS rule requires facilities to test Essential Caregivers (ECs). Given the breadth of the CMS definition of facility staff (see above), it appears that ECs could be included. However, the definition says "employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility," which raises a question, and we have asked MDH for guidance. Whether or not the CMS rule requires it, a facility may choose to test ECs. Given the role that

ECs play and their close contact with the residents they serve, we believe facilities should strongly consider including ECs in routine testing or asking ECs to provide documentation of testing.

How do you suggest we manage the documentation of outside provider testing?

Facilities are permitted to accept documentation from contractors or consultants instead of testing in the nursing home. To manage documentation for outside providers and contractors, please reach out to the agency and ask about their testing process including testing frequency. The outside agency must test on the same schedule (e.g. 2x/week, weekly, or monthly) as the LTC setting. If they do, the agency should send you test results. If they will not send you test results, they will need to send a written statement indicating their testing frequency, the employee(s) tested, and the outcome of those tests. If your testing frequency changes, you should continue to verify with the outside agency / contractor they continue testing with the same frequency as the LTC setting. If the outside agency/contractor is not testing on the same frequency as the LTC setting, you can include them in your testing process, should you choose. Or, if able, you can make arrangements to provide those services to the resident directly.

For routine testing, do staff have to give consent every time they are tested? **(New)**

There is no requirement to obtain and document a new consent each time you test staff, and employers may use a form on which staff consent to testing for a specified period of time. The consent form should provide employees with the opportunity to decline testing, and notify employees of their right to withdraw their consent at any time during the period covered by the form, knowing that declining or withdrawing may affect their ability to work. Employers with unionized employees should review the collective bargaining agreement when developing the consent form.

Frequency of Routine Testing & Checking the County Positivity Rate

How often must a facility do routine testing of staff? **(New)**

The frequency of routine staff testing is based on the county COVID-19 positivity rate, as follows:

Table 2: 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 turnaround time is <48 hours.**

The facility should begin testing all staff at the frequency prescribed in the Routine Testing table based on the county positivity rate reported in the past week.

For routine staff testing, how often to we have to check the positivity rates? How often do we have to change the frequency of our testing? **(New)**

Facilities should monitor their county positivity rate every other week (e.g., first and third Monday of every month) and adjust the frequency of performing staff testing according to the table above:

- If the county positivity rate increases to a higher level of activity, the facility should begin testing staff at the frequency shown in the table above as soon as the criteria for the higher activity are met.

- If the county positivity rate decreases to a lower level of activity, the facility should continue testing staff at the higher frequency level until the county positivity rate has remained at the lower activity level for at least two weeks before reducing testing frequency.

MDH addressed this question on its Sept. 9 long-term care COVID-19 call, and advised that each facility should establish a system and a consistent day when you are going to check the positivity rates every other week. If your system is to check every other Friday, for example, and a few days after you check you learn that CMS has posted new data or that positivity rates have changed, MDH advises facilities to stick with your plan. You will capture the new positivity rate data when you check it again on that Friday two weeks later, and adjust the frequency accordingly. Following the bullet points above, if you find the positivity rate has gone up (say from Medium to High), then the facility should immediately begin testing at the greater frequency; if the level has gone done (say from Medium to Low), the facility should continue testing at the higher frequency level until the county positivity rate has remained at the lower activity level for at least two weeks. Establish a written policy and procedure for checking the data every other week on a consistent day and document each time you check.

How do I find the county positivity rate that determines the frequency of routine staff testing? Do I use MN Department of Health Data or CMS data? **(Updated)**

Facilities should use CMS positivity rate data, not MDH data. CMS is posting positivity rates on its COVID-19 Nursing Home Data webpage. We have prepared this Tip Sheet: Determining Covid-19 Positivity Rate In Your County (08/31/20) to assist members in locating that data. CMS has posted data more than once-a-week since the rule was released, but we expect they will settle into a consistent process of updating weekly on a particular day of the week.

If we are in a situation of only needing to test monthly, can that first testing date be anytime in September?

In that situation, completing testing of all facility staff by the end of September would meet the requirement of the new rule. But note we are still working to understand MDH's survey expectations, and we would advise facilities to have the groundwork laid in advance, such as having a testing plan and policy in place that reflects the new requirements, having a lab arrangement established, and testing dates identified as soon as possible – in the event a survey team enters your building in early September.

Laboratory Issues

Reporting Testing Results

If our facility uses its point of care antigen testing machine, do we have to report the results? **(New)**

Yes. All sites conducting testing under CLIA certification or a CLIA Certificate of Waiver – including nursing homes - must report both positive and negative results within 24 hours to MDH. For each individual tested, all COVID-19 test results (positive and negative) performed by your facility must be reported to MDH.

Does the new requirement for us to report lab results apply to all tests done on our staff or only to tests our facility conducts using a point of care antigen testing machine?

The laboratory reporting requirement applies only when facilities run COVID-19 antigen tests on site. In that scenario, the facility is taking on the responsibilities of a laboratory and must report every antigen test conducted and its results, both positive and negative, to MDH within 24 hours. If an offsite laboratory runs your tests, that laboratory will report those results, both positive, and negative, to MDH.

How do we submit point of care antigen test results to MDH? **(New)**

Facilities will report results of COVID-19 antigen tests run on site using an Excel spreadsheet through a MDH COVID-19 Provider Portal. There is a standard spreadsheet, with many specific, defined data elements, and providers must use that template. Please contact MDH at Health.ELRmeaningfuluse@state.mn.us with questions about reporting or to receive an MDH Excel reporting template and access the portal. MDH maintains a separate electronic laboratory reporting system, but has stated that LTC facilities are not likely to be using this system at this time.

If labs are reporting test results, does that mean we should no longer report to MDH when we have a positive test in a staff member or resident? **(New)**

No. Reporting antigen test results does not replace responsibility to report clinical information about COVID-19 cases (e.g. through REDCap) as facilities have done since the start of the pandemic. There are two separate reporting requirements:

1) Laboratories must report patient level test results, both positive and negative, to MDH within 24 hours. When a nursing home runs an antigen test under its CLIA Certificate of Waiver, it is acting as a laboratory and must report the test results.

2) Nursing homes must report all positive cases in residents or staff to MDH, regardless of whether the positive result is obtained from an on-site antigen test or an offsite laboratory test. Information should be reported as soon as possible via a secure web form or by faxing the MDH COVID-19 case report form.

- The secure web-based case report form can be found at MDH: Web COVID-19 Patient Reporting Form (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=9XMX7WKRTM)
- The case report form for faxing can be found at MDH: COVID-19 Case Report Form (www.health.state.mn.us/diseases/coronavirus/hcp/covidreportform.pdf).

Does reporting positive lab results to MDH take the place of reporting positive cases to the National Healthcare Safety Network?

No. Nursing homes must also continue reporting COVID-19 data directly to CDC through the National Healthcare Safety Network (NHSN) system on a weekly basis. That data is not patient-specific lab results but facility-level data with aggregate numbers of positive cases and so forth. CDC recently update its Resident Impact and Facility Capacity data form to include information relating to antigen testing, but this is a separate and on-going reporting requirement.

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