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**Testing Requirements for Nursing Homes:   
Summary of New CMS Rule & Guidance**

**Revised: September 1, 2020**

On August 25th CMS released an [**Interim Final Rule**](http://r20.rs6.net/tn.jsp?f=001ep9K7hde3WKYBd-754-b6xr8iSss7ggnyi6ovQFSeQ26o2Ndmg-AF1YlhqXsX-OIAme3vPzhMzLPHIxl9Ol_zVLfpKmYnSqVpd-fIx5tlmVyiz_R9MUKwSCX0lk_MP6Fhl2GmBlEXE6YZ9iZ-hKA6IHBi9cH971bi2k9F8JhwPl2LsbjJrgZ-1Pg-b5UaCS5&c=uBrMxSmuK34C4VbgDgMWQ-O4z16-xHmgNqFrPlPqj7_9KB3I3KtEIw==&ch=L_O4AEwKY_7RvC9eHYib-AEAvUV8nVffsoFZtaVAhH5OHnKVvFSgIg==) 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. CMS has issued two memorandums that give detailed guidance about implementation of these requirements:

* [QSO-20-38-NH](https://www.cms.gov/files/document/qso-20-38-nh.pdf): Facility Testing Requirements and Revised COVID-19 Focused Survey Tool
* [QSO-20-37-CLIA,NH](https://www.cms.gov/files/document/qso-20-37-clianh.pdf): Requirements for Reporting of SARS-CoV-2 Test Results by (CLIA) Laboratories

In creating these testing requirements CMS has added new subsection 42 CFR § 483.80(h), and we have included that language in Attachment A below.

What follows is a high-level summary of these new requirements. LeadingAge Minnesota will continue to analyze the rule to assess implications for providers, flag questions where we need additional information from CMS and the MN Department of Health (MDH), and identify operational tools and resources that we can create to support members with implementation.

# Effective Date & Duration

**The rules are effective on September 2, 2020, and will be in effect for the duration of the Public Health Emergency relating to COVID-19.**

# Overview

Facilities are required to test both residents and staff in accordance with the parameters set out in QSO- 20-38-NH.

“Facility Staff” is defined broadly, to include 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. 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.

Facilities can meet the testing requirements through one or both of two diagnostic testing methods:

1. A molecular laboratory test (RT-PCR) through arrangement with an offsite laboratory. Laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected to rapidly inform infection prevention initiatives to prevent and limit transmission.
2. An antigen test using the rapid point-of-care diagnostic testing devices that CMS is distributing to all nursing homes that hold a CLIA Certificate of Waiver.

Note: an antibody test does not identify an active coronavirus infection; therefore, conducting an antibody test on a staff or resident would not meet the requirements.

**Note:** while CMS is authorizing use of point-of-care tests for purposes of compliance, distribution of those devices and tests is still ramping up, and most Minnesota nursing homes still have not received their shipment. (CMS estimates it will complete the distribution by Sept. 30). And, even when a facility has a point-of-care testing system, those tests will not suffice by themselves to meet the requirements, given that many antigen testing results will need to be confirmed through lab testing, and given the possibility that antigen test kits may be in short supply until later this year. As a result, it is critical for providers to work with your existing labs in planning for these new requirements.

# Testing Procedures

When prioritizing individuals to be tested, facilities should prioritize individuals with signs and symptoms of COVID-19 first, then perform testing triggered by an outbreak (as specified below):

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As shown above, procedures for testing staff are outlined in three separate categories within the memo:

*Staff with COVID-19 signs or symptoms* must be tested. While waiting for test results, the staff member(s) may not report to work. If testing confirms a staff diagnosis of COVID-19, follow the [CDC guidelines for return to work](https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html#:~:text=At%20least%2010%20days%20and%20up%20to%2020%20days%20have,consultation%20with%20infection%20control%20experts). This guidance was last updated on 08/10/2020. If testing for COVID-19 is negative, please follow facility policies to determine when staff may return to work.

*Residents with COVID-19 signs or symptoms* must be tested. While waiting for test results, residents should be placed on transmission-based precautions in accordance with [CDC guidelines](https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html). This means, droplet precautions and includes use of a gown, gloves, mask, and eye protection. If you do not have enough PPE, please see the [CDC PPE conservation strategies](https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html) information. Once the results are returned, if the resident is positive, continue droplet precautions until the resident has been fever free for 24-hours without the use of fever reducing medication AND it has been 10-days since symptom onset AND symptoms are improved. If the results are negative, take appropriate actions based upon the type of testing and your testing situation.

*Testing of staff and residents in response to an outbreak*. An outbreak means there is a new COVID-19 infection in any staff; or, any nursing home-onset COVID-19 resident infection. This does not include new admissions who are COVID-19 positive. When a single new case of COVID-19 is identified in staff or residents, all residents and staff should be tested. Serial testing must be completed every 3-7 days until there are no new positive cases for 14 days.

For staff or residents who test positive, you do not need to repeat a test for 90-days. A symptom-based approach should replace repeated testing. There is a possibility of persistent positive tests for at least 90-days and therefore testing previously positive staff or residents during that 3-month timeframe is not indicated. Please see the CDC guidance related to [discontinuing transmission-based precautions](https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html#:~:text=Note%3A%20For%20severely%20immunocompromised1,first%20positive%20viral%20diagnostic%20test.) and [healthcare worker return to work](https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html#:~:text=At%20least%2010%20days%20and%20up%20to%2020%20days%20have,consultation%20with%20infection%20control%20experts).

*Routine testing of staff* should be decided based on the county positivity rate. It is important not to confuse the county positivity rate with the county case rate:

* The **positivity rate** is the percent of COVID-19 tests with positive results. This is the measure CMS defines as driving staff testing frequency, and providers must use CMS data for this calculation. Minnesota does have this data published on their website, please do not use the number published by Minnesota, it is important to use the county positivity rate published by CMS. We have prepared this [**Tip Sheet: Determining Covid-19 Positivity Rate In Your County** (08/31/20)](https://www.leadingagemn.org/assets/docs/Tip_Sheet_for_Calculating_Positivity_Rate_in_Your_County.docx) to assist members in locating the CMS data.
* The **case rate** is the number of COVID-19 cases per 10,000 people. This is the measure MDH defines as a risk factor for determining whether to move to Level 2 Visitation. We use MDH data for this calculation, and MDH advises that providers should be informed of the level of community transmission by monitoring the 14-day case rate in their county. See our separate [**Tip Sheet Calculating Case Rate in Your Community**](https://www.leadingagemn.org/assets/docs/Tip_Sheet_Calculating_Case_Rate_in_Your_Community_081320.docx)**.**

The minimum requirement for monitoring the county positivity rate is once every other week. Testing frequency is triggered by the county positivity rate and is explained in the table below. As the county positivity rate changes, the testing frequency should be changed based upon the following table.

# Table 2: Routine Testing Intervals Vary by Community COVID-19 Activity Level

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| --- | --- | --- |
| **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.**

* **If the county positivity rate goes up** causing a need to increase the testing frequency, facilities should begin at the higher frequency right away.
* **If the county positivity rate goes down** the facility should not decrease the frequency of testing right away. Continue to test at the higher frequency until the county positivity rate remains at the reduced activity level for at least **two weeks**.

CMS expects lab results to be available in 48-hours; however, if the 48-hour turn-around time cannot be met, facilities are required to document its efforts to get lab results within the 48-hour time frame and contact with the local and state health departments.

# Refusal to Test

There are times when residents and/or staff may refuse to participate in testing if they are symptomatic. There are also times when a resident and/or staff member may refuse to participate in outbreak testing.

* *If* ***symptomatic*** *staff refuse to test* facilities must not allow symptomatic staff to work until the healthcare worker return to work criteria are met.
* *If* ***symptomatic or asymptomatic*** *staff refuse to participate in outbreak testing*, the staff member is not allowed to work until the outbreak testing process is complete.
* *If* ***symptomatic*** *residents refuse to test*, the symptomatic resident should be placed on transmission-based precautions until the criteria are met to discontinue precautions.
* *If* ***asymptomatic*** *residents refuse to participate in outbreak testing*, CMS states the facility should be “extremely vigilant, such as through additional monitoring, to ensure the resident maintains appropriate distance from other residents, wears a face covering, and practices effective hand hygiene” until outbreak testing is completed.

# Conducting Testing

Appropriate tests for symptomatic and outbreak testing of residents and staff include the PT-PCR lab test and the POC Antigen test. Antibody tests are not an acceptable test in these instances.

Just as with PT-PCR tests, Rapid POC testing devices require an order from a healthcare professional to perform the test. There are still many questions on antigen testing and the recommendations surrounding its use. MDH is working on a recommendations document for antigen testing. As soon as this document is posted, LeadingAge Minnesota will provide further information.

# Documentation of Testing

QSO- 20-38-NH includes detailed guidance on documentation facilities must complete to demonstrate timely compliance with the testing requirements, including documentation of:

* Testing conducted upon identification of symptomatic residents and staff and actions taken upon receipt of results.
* Testing and re-testing conducted following identification of a new COVID-19 case in the facility (i.e., outbreak), and demonstration that testing continued until no new cases are detected for 14 days.
* For routine testing of staff, documentation to show that the facility monitored its county positivity rate and activated the testing frequency corresponding with that rate (low, medium, high).
* How the facility addresses residents and staff that refuse testing or are unable to be tested, and
* If the facility is not able to meet a CMS standard, it must have documentation of the efforts it made to do so. For example, 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.

Strong documentation will very important, especially if there are cases where circumstances, such as limited lab capacity, impair a facility’s ability to comply with the new requirements. LeadingAge MN will develop tools to help members capture and record the information surveyors will be looking for.

# Survey & Enforcement of Testing Requirements

Surveyors will inspect nursing homes for adherence to the new testing requirements and deficient practices will be cited at new tag F886. Facilities that are cited may face enforcement sanctions based on the severity of the noncompliance, such as civil money penalties in excess of $400 per day, or over $8,000 for an instance of noncompliance.

Surveyors will review the facility’s documentation (see above) for compliance, and will also review records of residents and staff selected as a sample (3-4 in each category) as part of the survey process. If possible, surveyors should observe how the facility conducts testing in real-time.

CMS has revised the COVID-19 Focused Survey for Nursing Homes tool to reflect the new testing requirements, as well as other updates to help ensure an effective assessment of the facility’s compliance, and that revised tool is included as an attachment to QSO 20-38-NH (see link above).

* Note:CMS is also revising the survey process to include the assessment of compliance with the requirements for facilities to designate one or more individuals as the **infection preventionist(s)** who are responsible for the facility’s infection prevention and control program at 42 CFR § 483.80(b). Noncompliance related to this requirement will be cited at tag F882.

**CMS notes that, if a facility has documentation that demonstrates their attempts to perform and/or obtain testing in accordance with the 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.** Surveyors should also inform the state or local health authority of the facility’s lack of resources.

This acknowledgment is essential, given the challenges we know we will face with access to testing supplies, delays in receiving results from labs, and other resource challenges. We will advocate strongly both with CMS and MDH, for a survey process that does not penalize providers who are not able to meet all of these new standards due to forces beyond their control.

# Reporting Test Results

Facilities conducting point-of-care COVID-19 antigen tests under a CLIA Certificate of Waiver will be required to report data for all point-of-care tests the facility completes, at an individual patient level, within 24-hours of results being known.

Detail about methods for data submission, required data elements, and additional information can be found in [guidance](https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf) from the U.S. Dep’t of Health & Human Services and [related FAQs](https://www.hhs.gov/sites/default/files/laboratory-data-reporting-for-covid-19-testing-faqs.pdf). See also this MDH guidance

Where will the results be sent? That federal guidance states that data should be sent to state (or local) health departments to facilitate case investigations. **But note:** The MN Department of Health has not yet published guidance on the process for reporting point-of-care testing results. We are working with MDH to obtain this information. It’s possible CMS will also require facilities to submit test results to the National Healthcare Safety Network, but we don’t know that yet.

Compliance with this data reporting requirement is subject to CLIA survey oversight (a different division of MDH than the standard nursing home survey teams) and enforcement. If a facility does not report required test results, CMS will impose a fine of $1000 for the first day of noncompliance with the new reporting requirements, and $500 for each subsequent day the facility fails to report results.

# Next Steps

Even with the CMS guidance in hand, we know members have many questions about these new requirements and how to operationalize them. Our team has begun the work of creating additional tools and resources, and we will share them with you as soon as possible. Since the rule was first released, we have been in dialogue with MDH to develop a shared understanding of the requirements and to identify where more information is needed, including with regard to survey and enforcement.

Please contact [Jon Lips](mailto:jlips@leadingagemn.org) or [Kari Everson](mailto:keverson@leadingagemn.org) with any and all questions, comments and concerns, and we will incorporate those into our work with CMS and MDH.

# Attachment A: Specific Regulatory Language for Testing Requirement

