Long-Term Care Regulatory Provider Letter

Number: PL 20-46 (Revised)
Title: Reporting Guidance for Long-Term Care Providers – Point-of-Care Antigen Testing
Provider Types: Assisted Living Facility (ALF); <added> Intermediate Care Facility for Individuals with an Intellectual Disability or Related Conditions (ICF/IID); <added> Nursing Facility (NF)
Date Issued: November 30, 2020

1.0 Subject and Purpose

This provider letter outlines responsibilities related to reporting COVID-19 test results for providers conducting point-of-care (POC) antigen tests within their facilities. This letter is not intended for use by providers who do not conduct COVID-19 POC tests within their facility. Providers who do not conduct COVID-19 POC tests within their facility can refer to PL 20-37. <added> This letter has been revised to include information for ICF providers offering point-of-care testing for COVID-19 and to clarify test reporting requirements for NFs. <added>

2.0 Policy Details & Provider Responsibilities

Facilities conducting a COVID-19 POC antigen test within their facilities must apply for a CLIA waiver and <added> comply with all applicable reporting requirements. <added> The following sections describe each requirement.

2.1 CLIA Waivers

NFs receiving POC antigen test kits from the U.S. Department of Health and Human Services, ALFs purchasing or receiving POC antigen test kits for COVID-19, <added> and ICFs purchasing or receiving POC antigen test kits for COVID-19 <added> will need to obtain a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver

before any testing can be conducted. Additionally, ALFs, <added> ICFs, <added> and NFs without a CLIA Certificate of Wavier are encouraged to apply so that they may participate in any future testing initiatives should they occur. Facilities can apply for a CLIA waiver by filling out Form CMS-116 and sending it to the regional CLIA licensing group for the zone where the facility is located.

Facilities that have an existing CLIA Certificate of Waiver and are using a waived COVID-19 test are not required to update the CLIA Certificate of Waiver. As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." The Food and Drug Administration determines which tests meet these criteria when it reviews a manufacturer's applications for test system waiver.

2.2 Reporting COVID-19 Test Results:

Facilities offering POC antigen testing related to COVID-19 must report data for all testing completed, for all test results (positive, negative or indeterminate), and for each individual tested (residents and staff). A facility must report the test results within 24 hours of the results being known or determined, on a daily basis. For days that a facility does not conduct any tests, the facility would not have to submit a report.

<this section is new>

2.2.1 Reporting to NHSN

NFs are now required to report antigen test information through the National Healthcare Safety Network (NHSN)[1]. Reporting antigen test results through the NHSN is optional for ALFs and ICFs.

The Texas Department of State Health Services (DSHS) receives test result data from NHSN, which means that facilities fulfill the state requirement to report test result data to DSHS by reporting test result data to NHSN. However, NHSN does *not* report to local health departments; facilities reporting test result data to

[1] QSO 20-37-CLIA, NH and Reporting Guidance from Secretary of HHS

NHSN must still report test data to their local health department[2]. Reporting antigen test results through NHSN requires Level-3 SAMS access. Providers must report antigen test results to DSHS while awaiting approval for Level-3 SAMS access in NHSN.

ALFs and ICFs choosing to report test data through the NHSN should follow the 5-step Enrollment for Long-term Care Facilities instructions before applying for Level-3 SAMS Access.

Applying for Level-3 SAMS access: To submit antigen test result data to NHSN, employees responsible for reporting must complete the Secure Access Management Services (SAMS) identity verification process to be migrated to a level-3 SAMS access in NHSN. The identity verification process is outlined below and detailed on this webpage. Each employee who submits testing data must complete the process to be migrated to a level-3 SAMS access.

- In October, the federal Centers for Disease Control and Prevention (CDC) sent emails to individuals enrolled in the NHSN COVID-19 module with instructions to upgrade to a level-3 SAMS access. Check your email inbox for communication from SAMS, via sams-no-reply@cdc.gov, requesting two forms of identification (ID). If you are unable to locate the email, contact NHSN@cdc.gov and include in the subject line, "Enhancing Data Security."
    - Locate identification documents included on the list of SAMS identity verification documents.
    - Log into SAMS at http://sams.cdc.gov and use the Update Profile menu option on the left side of the page. Confirm that your home mailing address is correct and current within your SAMS profile.
    - Ensure your name and address match how it appears on the documents you plan to submit to SAMS.
    - Submit the identification forms as directed in the email received from SAMS.

[2] Executive Order GA-10

- Once confirmed, SAMS will send you a "Welcome to SAMS" email. A SAMS grid card will be mailed to your residential/home address by USPS mail. The SAMS grid card permits Level-3 access to NHSN.
- After receiving your SAMS grid card, be sure to log into SAMS at http://sams.cdc.gov. Underneath the NHSN System header, please select the "NHSN Reporting" link. DO NOT access the "NHSN LTC Reporting" option, as this option will direct you to level one security.
    - If you experience problems during enrollment, please contact the NHSN user support nhsn@cdc.gov with "Enhancing Data Security" in the subject line.
    - Once enrolled in level-3 SAMS access, NFs can contact nhsn@cdc.gov for assistance with submitting test result data. TMF Health Quality Institute also provides assistance with NHSN reporting, which can be reached by contacting nhnetwork@tmf.org.

2.2.2 Reporting to DSHS

<added> The following steps outline what is needed to begin reporting to DSHS. Reporting test result data to DSHS is required for all facilities that do not report test result data through NHSN[3]. <added> Once you have CLIA or a CLIA waiver:

1. Register here: https://www.dshs.state.tx.us/coronavirus/forms/registerlab.aspx
2. Submit the online registration webform.
3. Complete DSHS onboarding process.
4. Submit required testing data to DSHS.

DSHS is considering alternative solutions for registering and onboarding that would create a more simplified, streamlined method for uploading electronic lab results. Facilities that have made every attempt to register with DSHS but are unable to complete the registration must keep all test-result

[3] Executive Order GA-10

documentation until the facility is able to submit the testing data. Once the facility successfully registers via the DSHS reporting system (or alternative method created by DSHS), the facility will then submit all previous testing result data.

Facilities can contact DSHS at COVID-19ELR@dshs.texas.gov with any questions related to registration or reporting through DSHS.

2.2.3 Reporting to the Local Health Department

<added> All facilities conducting COVID-19 antigen tests must report test result data to their local health department (LHD) or to the DSHS Region if there is not a local health department[4]. <added>

1. Locate the LHD or DSHS Region for the area in which the facility is located: https://www.dshs.texas.gov/regions/2019-nCoV-Local-Health-Entities/
2. The LHD or DSHS region will inform providers of any required reporting forms and processes.
3. The required data is submitted to the LHD or DSHS Region for the area in which the facility is located, using the forms and processes indicated.[5]

2.3 Reporting Confirmed Cases & Additional Reporting Information for all NF and ALF Providers

In addition to reporting requirements related to COVID-19 POC antigen test results, NFs, <added> ICFs, and <added> ALFs must adhere to the reporting requirements outlined in PL 20-37.

3.0 Background/History

CMS began shipping POC antigen test kits to NFs with a CLIA waiver or CLIA certificate in July 2020. ALFs <added> and ICFs <added> have also received POC antigen test kits, and therefore a CLIA waiver is also required. POC antigen tests quickly detect fragments of proteins found on or within

[4] Executive Order GA-10

the virus by testing samples collected from the nasal cavity using swabs. Previously, the associated requirements for <added> NFs, ICFs, and ALFs <added> conducting POC antigen tests for COVID-19 were located in several different locations. This letter consolidates reporting requirements into one place.

4.0 Resources

CDC guidance for antigen testing in nursing homes and using antigen tests

PL 20-37: Reporting Guidance for Long-term Care Providers

CMS FAQ: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes

5.0 Contact Information

If you have any questions about this letter, please contact the Policy, Rules and Training Section by email at PolicyRulesTraining@hhsc.state.tx.us or call (512) 438-3161.