CLINICAL LABORATORY IMPROVEMENT AMENDMENT CHANGES POST-PHE

CMS recently published memo QSO-23-15-CLIA, outlining the impact of the ending of the Public Health Emergency (PHE) on the Clinical Laboratory Improvement Amendments (CLIA) requirements and flexibilities implemented during the COVID-19 pandemic.

The key changes impacting long term care providers operating under CLIA Certificates of Waivers (CoW) are identified below.

- **COVID-19 Test Result Reporting Requirements:** During the PHE, all providers operating under a CLIA waiver that performed a COVID-19 test were required to report the results of each test. Because CMS only has authority to require reporting during the PHE, the CLIA requirement to report COVID-19 results ended when the PHE was terminated on May 11, 2023. Two important caveats regarding the ending of this requirement are as follows:
    - Facilities are still required to report COVID-19 information, including positive test results, to the NHSN under CMS-5531-IFC.
    - Individual states may have reporting requirements in place, so providers should verify any state reporting requirements before discontinuing the reporting of test results.

- **Molecular and Antigen Point of Care Test Asymptomatic Testing:** Many FDA-approved COVID-19 molecular and antigen point of care (POC) tests are authorized only for use on symptomatic individuals. During the PHE, CMS allowed laboratories to use these tests on asymptomatic individuals. This flexibility was important for SNFs and ALFs, as they commonly used these POC tests on asymptomatic individuals to meet CMS and state requirements to conduct screening testing of staff, regardless of symptoms. This flexibility has been phased out with the end of the PHE. **All CLIA-certified settings are now required to follow the manufacturer's Instructions for Use (IFU) for testing.** CLIA will not consider it a modification, however, if the IFU states, "individuals suspected of COVID-19 by their health care provider", and the test is ordered by the health care provider for asymptomatic patients. The decision if an individual is suspected of COVID-19 is made by the health care provider.

- **Use of Expired Reagents During the PHE:** CMS allowed laboratories to use expired reagents due to COVID-19 reagent supply problems. CMS has determined that at the end of the PHE, laboratories will no longer be able to continue using expired reagents.

Finally, in the FAQ section at the end of the memo, CMS provides clarification regarding use of tests that are Emergency Use Authorized for use under a CLIA Certificate of Waiver. CMS states, *"Laboratories with a Certificate of Waiver (CoW) will continue to be eligible to perform testing for as long as the test's Emergency Use Authorization remains in effect. Once the assay has gone through the FDA's full traditional marketing authorization, it will receive CLIA complexity categorization. If the test remains categorized as waived, no further action would be necessary."*

All changes are effective immediately. Members are encouraged to review QSO-23-15-CLIA for a complete list of changes. Please contact COVID19@ahca.org with any questions.