DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-25-CLIA

DATE: September 26th, 2022

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: CMS Rescinds December 7, 2020, Enforcement Discretion for the Use of SARS-CoV-2 Tests on Asymptomatic Individuals Outside of the Test's Instructions for Use

Memorandum Summary

CMS is issuing this memorandum to rescind the December 7, 2020 guidance regarding the enforcement discretion under CLIA for the use of tests for SARS-CoV-2 on asymptomatic individuals outside of the test's authorization, when an Emergency Use Authorization has been granted by the FDA.

EFFECTIVE IMMEDIATELY:

- CMS is rescinding the enforcement discretion that allowed Certificate of Waiver labs to perform SARS-CoV-2 molecular and antigen Point of Care (POC) tests on asymptomatic individuals outside of the test's authorization.
- CMS is also rescinding the enforcement discretion that allowed non-waived labs to perform SARS-CoV-2 molecular and antigen tests on asymptomatic individuals outside of the test's authorization without establishing performance specifications.
- All CLIA certified laboratories are required to follow the manufacturer's instructions for use with regards to the intended use for SARS-CoV-2.
- In order to use any test for SARS-CoV-2 outside of the test's authorization, a laboratory must be a high-complexity laboratory.
- In addition, the laboratory must establish performance specifications as required by the CLIA regulations at 42 CFR 493.1253 before reporting patient test results.

Background:

CMS continues taking critical steps to ensure America's clinical laboratories can respond to the threat of COVID-19 and other respiratory illnesses to ensure patient health and safety. The CLIA program intends to ensure that test results provided to individuals and their health care providers are accurate and reliable. Due to the public

health emergency posed by COVID-19 and the urgent need to expand laboratory capacity, on December 7, 2020, CMS announced that we would exercise enforcement discretion under CLIA for the duration of the Public Health Emergency for the use of authorized tests for SARS-CoV-2 molecular and antigen Point of Care (POC) on asymptomatic individuals outside of the test's authorization by Certificate of Waiver laboratories when the FDA has granted an Emergency Use Authorization. Additionally, CMS announced that laboratories performing non-waived testing would not be cited for performing molecular or antigen tests on asymptomatic patients outside of the test's authorization without establishing performance specifications as required by regulation under CLIA.

We are rescinding CLIA guidance related to the enforcement discretion allowed during the COVID-19 public health emergency regarding the use of tests on asymptomatic individuals outside of the test's authorization when the FDA has granted an Emergency Use Authorization. Laboratories that are accredited must follow Accreditation Organization (AO) standards. All laboratories also need to follow any State laws governing laboratories, which may be more stringent than CLIA.

Discussion:

CMS issues this memorandum to rescind the enforcement discretion under CLIA related to the use of tests on asymptomatic individuals outside of the test's instructions for use. As home testing is now widely available and tests can be provided within the parameters designed to ensure accuracy, the original justification supporting this policy is no longer compelling.

All CLIA-certified laboratories are required to follow the manufacturer's instructions for use with regard to the intended use for SARS-CoV-2. Under the CLIA regulations, in order to perform testing, a facility must be a CLIA-certified laboratory that meets applicable regulatory requirements appropriate for the complexity designation of the test. Any test for which the instructions for use have been modified becomes a high-complexity test.

If a test is modified, the laboratory must establish performance specifications as required at §493.1253 (b)(2). It is the laboratory director's responsibility to ensure that the procedures used to establish performance specifications are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method (e.g., number of samples), and that the test method can provide the quality of results required for patient care. You may access the CLIA regulations at CLIA Regulations

CLIA surveyors will cite a facility if it performs SARS-CoV-2 molecular and antigen POC tests on asymptomatic individuals outside the test's authorization. Additionally, CLIA surveyors will cite a facility when tests are performed in such a manner without establishing performance specifications.

Contact:

For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov.

Effective Date:
The rescission of this policy is effective immediately. This policy should be communicated to all survey and certification staff and managers immediately. Laboratories will be granted 30 days from the date of this memorandum to come into compliance.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group