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CMS Takes Action to Protect Integrity of COVID-19 Testing

Agency issues cease and desist letters to laboratories testing without appropriate certification

The Centers for Medicare & Medicaid Services (CMS) is taking every action to ensure U.S. laboratories are fit to deliver reliable, accurate and timely patient test results for coronavirus disease 2019 (COVID-19) by confirming Clinical Laboratory Improvement Amendments of 1988 (CLIA) certifications are up- to-date. A recent record check by CMS resulted in the issuance of 171 cease and desist letters to facilities that did not have proper CLIA certifications in place. CLIA certification is important because it verifies that laboratories meet federal performance, quality and safety standards to properly diagnose, prevent and treat diseases.

“Testing capacity has rightly been at the top of President Trump’s priority list since the early stages of this pandemic,” said CMS Administrator Seema Verma. “But we also understood that for testing to fulfill its potential, tests must be reliable. Today’s announcement will help ensure that Americans can rest secure that they will receive test results that are both fast, accurate, and trustworthy.”

Every facility that conducts COVID-19 testing is considered a “laboratory” and must be certified under CLIA. To make certification easy, CMS implemented an expedited review process at the beginning of the public health emergency and recently [released](#) a quick-start guide that helps laboratories with the application process. It is imperative to public safety that facilities apply for CLIA certification and only operate within the scope of that certification to prevent false results that could adversely alter diagnosis, treatments and contribute to the further spread of COVID-19.

Since August 12, 2020, CMS issued 171 cease and desist letters to entities across the U.S. that were testing for COVID-19 without an appropriate CLIA certificate. Of those 171 letters, 34 percent went to facilities conducting laboratory testing without a CLIA certificate and 66 percent were issued to laboratories performing COVID-19 testing outside the scope of the existing CLIA certification. The letters ordered these laboratories to stop immediately to safeguard the integrity of COVID-19 testing, and protect patients from potential endangerment if provided

inaccurate or unreliable test results. Following receipt of the letter, laboratories are required to provide CMS an attestation certifying they have ceased testing.

In the letters, CMS provided non-certified laboratories with information on how to become CLIA certified and encouraged certified laboratories to obtain the proper CLIA certification to resume testing. CMS has taken this action to promote compliance with CLIA and keep patients safe.

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