

Clinical Laboratory Improvement Amendments (CLIA)

MEDICARE PROVIDER NEWS & EDUCATION

wellcare



CLIA

The Clinical Laboratory Improvement Amendments of 1988 is federal legislation with the objective of ensuring quality laboratory testing (Section 353; Public Health Services Act, 42 United States Code §263a – Certification of laboratories) and Centers for Medicare & Medicaid Services Title 42 CFR Part 493. It applies to any facility or individual Provider that performs laboratory services and wants to receive payments under Medicare and Medicaid programs.



Staying Compliant

Wellcare will continue to uphold the Federal guidelines to ensure laboratory claims submitted by providers meet these requirements:

- ✓ A valid CLIA certificate for the type of tests you are performing for each location*
- ✓ An active CLIA certificate

* Exceptions: mobile labs, Not-for-profit or Federal, State or local government laboratories and laboratories located within a hospital campus.



Types of CLIA Certificates:

Certificate of Waiver	<ul style="list-style-type: none">• Lab only performs waived testing that is simple and routine in nature.
Certificate for PPM	<ul style="list-style-type: none">• Labs where a physician, mid-level practitioner or dentist perform specific microscopy procedures• Limited to PPM Procedures• Labs also perform waived testing
Certificate of Registration	<ul style="list-style-type: none">• Initial certification provided to a laboratory while awaiting its Certificate of Compliance or Certificate of Accreditation• Performs moderate and/or high complexity testing as well as waived tests• The COR expires after 2 years or when the laboratory meets certification requirements (whichever is sooner)
Certification of Compliance	<ul style="list-style-type: none">• Labs perform moderate and/or high complexity testing and waived testing
Certificate of Accreditation	<ul style="list-style-type: none">• Labs perform moderate and/or high complexity testing and waived testing



Claims Submission

Providers should submit their CLIA number on the claim as follows:

- ✓ Electronic Claim: Loop 2300, REF01 = X4, REF02
- ✓ Paper Claim (CMS 1500): Field 23
 - If there are multiple items in Box 23, the provider should include a hyphen (-) or semicolon (;) between the items



Where Can I Find More Information on CLIA

For more information on the specific types of certifications visit:

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html



Other Resources

- CMS: <https://www.cms.gov>
- CDC: <https://www.cdc.gov>
- FDA: <https://www.fda.gov>



Additional Questions?

Please contact Customer Service for assistance with your questions or concerns.