CLIA Certificate Editing

Aetna Better Health adheres to Federal guidelines concerning laboratory services (Section 353; Public Health Services Act, 42 United States Code §263a and Centers for Medicare & Medicaid Services Title 42 CFR Part 493). Laboratory claims submitted by providers must show evidence of compliance with federal legislation having the objective of ensuring quality laboratory testing performed pursuant to valid and active CLIA certificates for laboratory procedures, tests, and locations.

Providers 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/downloads/howobtaincliacertificate.pdf

Other Resources

Three federal agencies are responsible for CLIA: The Food and Drug Administration (FDA), Center for Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC). Each agency has a unique role in assuring quality laboratory testing.

Regulatory Agency	Role	Website
FDA	• Categorizes tests based on complexity • Reviews requests for Waiver by Application • Develops rules/guidance for CLIA complexity categorization	https://www.fda.gov
CMS	• Issues laboratory certificates • Conducts inspections and enforces regulatory compliance • Publishes CLIA rules and regulations	https://www.cms.gov
CDC	• Develops technical standards and laboratory practice guidelines, including standards and guidelines for cytology • Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC)	https://www.cdc.gov