Anthem Blue Cross

CMS Required CLIA Certification Number for Labs: Change to Medicare Advantage Claims Processing

**Background:** Effective 7/1/2015, Anthem Blue Cross implemented an edit for Blue Individual Medicare Advantage medical claims. Claims are now denied if the Centers for Medicare & Medicaid Services required CLIA (Clinical Laboratory Improvement Amendments) certification is missing or invalid.

The edit applies only to individual Medicare Advantage claims. The edit does not apply to group-sponsored (EGR) claims. Providers were notified of this change via Network Update in February 2015 with a reminder in June 2015. Beginning in April 2015, providers who billed laboratory codes that require certification received a remittance reminder to include the correct information when billing for laboratory codes.

Please note that the CLIA coding requirements outlined below also are required for original Medicare claims.

**CLIA FAQs**

**What are the Clinical Laboratory Improvement Amendments?**
The Clinical Laboratory Improvement Amendments (CLIA) establish quality standards for all non-research laboratory testing performed on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. CMS administers the CLIA laboratory certification program.

**Why did Anthem start requiring CLIA certification in July 2015?**
Anthem wants to help ensure claims are properly coded and align with CMS requirements.

**If the CLIA number is not present on the claim form will the claim deny?**
Yes. The claim will deny back to the submitter if the CLIA number is missing or invalid. The missing or invalid CLIA number will be denied with denial Code GLI.

**What field should a provider use to bill their CLIA certification number?**
The CLIA number is located in the following fields according to claim type:
- Electronic Data Interchange (EDI) format -- Loop 2300, REF01 = X4, REF02
- CMS 1500 Paper Form – Field 23

**How should a provider bill a claim that requires more than one CLIA certification or a prior authorization number and CLIA certification?**
If billing more than one item in field 23 of the CMS 1500 form, the provider must include a hyphen (-) or semicolon (;) between the items.

**How are test methods categorized?**
CLIA regulations are based on the complexity of the test method. Providers should ensure they bill the correct CLIA certification for the complexity of the test method billed. Test methods are categorized into three levels of complexity:
• Waived Complexity
• Moderate Complexity, including Provider-Performed Microscopy Procedures (PPMP)
• High Complexity

The more complicated the test, the more stringent the requirements.

There are five CLIA provider certificate types:

• **Certificate of Waiver (CW)**
  - Eligible to bill CLIA Code Category Level 1
  - The CW permits a laboratory to perform only waived tests. Waived tests are so simple and accurate that little risk of error exists when done correctly.

• **Certificate for Provider-Performed Microscopy Procedures (PPMP)**
  - Eligible to bill CLIA Code Category Level 1 and 2
  - A subset of the moderate complexity tests, PPMPs receive a unique classification and certification. A laboratory in which a physician, mid-level practitioner, or dentist performs only certain microscopy procedures and waived tests may receive this certificate.

• **Certificate of Registration (COR)**
  - Eligible to bill CLIA Code Category Level 1, 2 and 3
  - A laboratory that applies for a Certificate of Compliance (COC) or Certificate of Accreditation (COA) receives a COR. A COR provides temporary certification for the laboratory to conduct moderate and high complexity tests while it completes the certification process. The COR expires after two years or when the laboratory meets certification requirements (whichever is sooner).

• **Certificate of Compliance (COC)**
  - Eligible to bill CLIA Code Category Levels 1, 2 and 3
  - A laboratory may receive a COC after an on-site survey finds that it complies with all applicable CLIA requirements. Laboratories with a COC that perform moderate and high complexity tests must be surveyed every two years.

• **Certificate of Accreditation (COA)**
  - Eligible to bill CLIA Code Category Levels 1, 2 or 3
  - A laboratory that performs moderate and high complexity tests and meets the standards of one of seven private non-profit accreditation organizations, approved by CMS, may receive a COA. Each year, CMS evaluates the organization's performance enforcing CLIA requirements.

**Where can I learn more?**
For more information on the Clinical Laboratory Improvement Amendments, please visit the following website: CMS CLIA Information Page;

http://www.cms.hhs.gov/clia/

If you have any questions, please contact the Provider Services number on the back of the member’s ID card.

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