

MEDICARE REIMBURSEMENT:

What You Need to Know Regarding Your CLIA Certificate

The Centers for Medicare & Medicaid Services (CMS) instructed local Medicare carriers to deny claims for laboratory testing in the physician office laboratory beginning July 1, 1997. Prior to this time, CMS limited its denial of Medicare payments to independent and hospital laboratories who are not properly certified for CLIA. As a result of this change in policy, physician office laboratories first became subject to claims denial for CLIA-related reasons.

According to CMS, Medicare claims are denied for two reasons: 1) the laboratory's CLIA certification has expired; and/or 2) the laboratory bills Medicare for tests for which the laboratory is not properly certified (i.e., billing for tests beyond the laboratory's CLIA certificate).

COLA has developed this Fast Facts to clarify the approach CMS takes to implement claims denial, precautions the Agency takes to minimize unnecessary denials, and how your laboratory can respond to "alerts" or billing problems which may arise.

Receive an Alert = Take Corrective Action

If there is a problem, your laboratory will receive an "alert" or warning from CMS or the local Medicare carrier prior to claims denial. If you receive an alert, promptly contact your State Survey Agency or local carrier for guidance on how to address any CLIA compliance issues.

Lab directors correcting CLIA compliance problems will not be denied Medicare payments. However, lab directors who fail to respond to the alert will have their claims denied for the laboratory tests in question. Back payment will not be made for denied claims unless CMS determines that the laboratory was actually in good standing at the time the denied claims were submitted.



There can be any number of reasons why your laboratory received an alert. These reasons include, but are not limited to, billing beyond your certificate, failure to renew your certificate, and/or overdue CLIA fees.

The important thing is to immediately respond to an alert. Generally, you should contact your state survey agency first, unless the alert specifically states that the problem is related to a coding mistake. If the problem is related to coding, you should contact your local carrier. Physician office laboratories who do not receive an "alert" are probably in good standing, requiring no action on their part.

CMS has implemented the “alert” mechanism described above to give physician office laboratories a final opportunity to correct any CLIA compliance issues. As an added precaution against unnecessary claims denials, the CMS Regional Office must verify that a laboratory is non-compliant before the local carrier can deny the claims in question.

Failure to possess a current CLIA certificate does not, in and of itself, mean that you will be denied payment. Your CLIA number should still be valid in the CMS system.

Only if you receive an “alert” do you need to contact your State Survey Agency to verify you are in good standing or to take actions to restore compliance.

CPT Coding Issues

CMS has indicated that in many cases “coding errors” can result in a laboratory inadvertently billing beyond its CLIA certificate. For example, the methodology used to perform a rapid strep A test can be classified by CMS as a “waived” or “moderate” complexity test. All tests classified as waived or provider-performed microscopy have their own unique CPT codes. If your waived laboratory fails to use the unique CPT code for “strep A - waived,” you will be denied payment for billing beyond your laboratory certificate.

Directions on where to find the correct CPT codes for waived and provider-performed microscopy are noted in the table at right. COLA recommends that you share these resources with your billing staff to make sure they understand the unique CPT codes for the simplest testing. If you have additional questions regarding coding issues, you should contact your local carrier.

CMS 1500 Form

In October 1997, CMS began to require laboratories to include their CLIA number on the CMS 1500 claim form. Spot #23 is the location on the 1500 form for the CLIA number. All laboratories are required to report their CLIA numbers or claims will be denied.

Conclusion

CMS implementation of Medicare denials has caused a great deal of concern among physicians and their laboratory staff. If you have not received an “alert” you should remain at ease and trust that your CLIA compliance is in good standing. If you do receive an “alert,” act swiftly and contact your State Survey Agency. If you failed to act when you received your alert, do so now so that you can prevent future denials.

Should you require additional assistance from COLA, please call our Information Resource Center toll-free at (800) 981-9883.

CPT Codes for Waived Tests

Waived testing procedures are those tests classified under CLIA as waived and requiring only a certificate of waiver to be performed. There are no personnel standards nor proficiency testing requirements. However, labs performing waived tests are expected to follow good laboratory practices, such as following manufacturer’s instructions. In addition, federally waived tests may not be recognized as waived by your state, such as New Jersey. Please contact your state agency for specific information.

For a current listing of waived tests and their CPT codes visit: <http://www.cms.hhs.gov/CLIA/downloads/CR5484.waivedtbl.pdf>

CPT Codes for Provider-Performed Microscopy Procedures

Tests classified under CLIA as Provider-Performed Microscopy Procedures (PPMP) may be performed by: physicians, dentists, nurse practitioners, nurse midwives, and physician assistants. A PPM certificate allows qualified personnel to perform PPM as well as allowing any person to perform waived tests.

Proficiency testing (PT) is recommended for urine sediments, pinworm examinations, and KOH preps. All other CLIA guidelines for moderate complexity testing, such as quality control, procedure manuals, and quality assurance, are required for PPM procedures.

For a current listing of PPM tests and their CPT codes visit: <http://www.cms.hhs.gov/CLIA/downloads/ppmp.list.pdf>