

## Introduction

This specialty manual is linked to the appropriate sections of the Online CMS (Centers for Medicare & Medicaid Services) Manual System for your convenience and to assure that you always have access to the most up-to-date information on guidelines relating to this specialty.

CMS transitioned to a Web-based system in 2003. Their system is called the Online CMS Manual System and is located at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html>. The Online Manual System is organized by functional area and includes guidelines affecting all of Medicare (i.e. Part A (Hospital Services, Part B (Medical Services, etc.).

To use this manual, simply locate the topic of interest and note the corresponding section of the Online CMS Manual System, then click on the link to the Online CMS Manual System. This takes you to the appropriate Publication and Chapter; you then review the Table of Contents for your specific topic/section number. Most chapters in the Online CMS Manual allow you to click on the specific section in the Table of Contents which takes you directly to that section in the chapter. Other chapters require that you scroll through the chapter to find the section noted in the specialty manual.

## Disclaimer

This manual has been prepared as a tool to assist providers. Every reasonable effort has been made to assure the accuracy of the information; however, the ultimate responsibility for correct billing lies with the provider of the services.

CGS, Medicare Outreach and Education, their employees and their staff make no representation, warranty or guarantee that this compilation of Medicare information is all inclusive or error-free and will bear no responsibility for the results or consequences of the use of this manual. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings.

## Medicare Claims Processing Manual

### Chapter 16 - Laboratory Services

CMS Manual System, Pub. 100-4, Medicare Claims Processing Manual, Chapter 16 <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c16.pdf>

- Section 10, Definitions relating to Laboratory Services
- Section 20, Calculation of Payment Rates – Clinical Laboratory Fee Schedules
- Section 30, Special Payment Considerations
- Section 40, Billing for Clinical Laboratory Test
- Section 50, Carrier Claims Processing
- Section 60, Specimen Collection Allowance and Travel Fees
- Section 70, Clinical Laboratory Improvement Amendments (CLIA) Requirements
- Section 80, Issues Related to Specific Tests
- Section 90, Automated Profile Tests and Organ/Disease Oriented Panels
- Section 100, CPT Codes Subject to an Not Subject to the Clinical Laboratory Fee Schedule
- Section 110, Coordination between Carriers and Other Entities
- Section 120, Clinical Laboratory Services Based on the Negotiated Rulemaking

CMS Manual System, Pub. 100-3, Medicare National Coverage Determinations Manual Chapter 1, Part 3, Section 190 [http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1\\_Part3.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part3.pdf)

## CLIA Web Page

CLIA Application for Certification <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/>

CLIA Brochures <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>

Demonstration Project for Competitive Bidding of Clinical Laboratory Services <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>

Physician Performed Microscopy Procedure (PPMP) <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/ppmpfr2001.pdf>

Pub 100-4, Chapter 16, Section 70.6 <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c16.pdf>

Physician Pathology Services – Technical Component <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1148CP.pdf>

Pub 100-4, Chapter 16, Section 80 <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c16.pdf>

Hematology, Cytopathology, and Blood Banking Services <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R382CP.pdf>

Pub 100-4, Chapter 12, Section 60 <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>



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