CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11463	**Date: June 23, 2022**
	Change Request 12766

SUBJECT: Internet Only Manual Update to Publication 100-04, Chapter 16, Sections 70.5, 70.8, and 70.9 to Remove References to the Clinical Laboratory Improvement Amendments (CLIA) Files

I. SUMMARY OF CHANGES: The purpose of this change request is to remove the reference of CLIA files in the claims processing manual, publication 100.04, chapter 16, sections 70.5, 70.8, and 70.9.

EFFECTIVE DATE: July 25, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 25, 2022

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	16/70.5/CLIA Categories and Subcategories
R	16/70.8/Certificate of Waiver
R	16/70.9/HCPCS Subject to and Excluded from CLIA Edits

III. FUNDING:

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal:11463	Date: June 23, 2022	Change Request: 12766

SUBJECT: Internet Only Manual Update to Publication 100-04, Chapter 16, Sections 70.5, 70.8, and 70.9 to Remove References to the Clinical Laboratory Improvement Amendments (CLIA) Files

EFFECTIVE DATE: July 25, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 25, 2022

I. GENERAL INFORMATION

A. Background: The purpose of this change request is to revise the claims processing manual, publication 100-04, chapter 16, sections 70.5, 70.8, and 70.9. These changes are being made to remove the references to the CLIA files https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf and http://www.cms.hhs.gov/CLIA/downloads/cpt4exc.pdf.

These files are mentioned in the following chapter 16 sections:

- 70.5 - CLIA Categories and Subcategories
- 70.8 - Certificate of Waiver
- 70.9 - Healthcare Common Procedure Coding System Subject To and Excluded From CLIA Edits

Information regarding CLIA test complexity categorization can be found by searching the U.S. Food and Drug Administration website (www.fda.gov).

B. Policy: This change is intended only to remove the mentioning of the CLIA files and no policy, processing, or system changes are anticipated.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12766.1	Contractors shall be aware of the removal of the website and CLIA files titled: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf and http://www.cms.hhs.gov/CLIA/downloads/cpt4exc.pdf mentioned in the CMS Internet Only Manual (IOM) Publication 100-04, Chapter 16- Laboratory Services, subsections 70.5, 70.8, and 70.9.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12766.2	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.		X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Vickie Poff, 410-786-0836 or vickie.poff1@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

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70.5 - CLIA Categories and Subcategories

(Rev. 11463; Issued: 06-23-22; Effective: 07-25-22; Implementation: 07-25-22)

A laboratory may be licensed or exempted from licensure in several major categories of procedures. These major categories are:

Category Number	Category/Subcategory Name
010	Histocompatibility
100	Microbiology
110	Bacteriology
115	Mycobacteriology
120	Mycology
130	Parasitology
140	Virology
150	Other Microbiology
200	Diagnostic Immunology
210	Syphilis Serology
220	General Immunology
300	Chemistry
310	Routine
320	Urinalysis
330	Endocrinology
340	Toxicology
350	Other
400	Hematology
500	Immuno-hematology
510	ABO Group and RH Type
520	Antibody Detection (Transfusion)
530	Antibody Detection (Non Transfusion)
540	Antibody Identification
550	Compatability Testing
560	Other
600	Pathology
610	Histopathology
620	Oral Pathology
630	Cytology
800	Radioassay
900	Clinical Cytogenics

Information regarding CLIA test complexity categorization can be found by searching the U.S. Food and Drug Administration website (www.fda.gov).

70.8 - Certificate of Waiver

(Rev. 11463; Issued: 06-23-22; Effective: 07-25-22; Implementation: 07-25-22)

Effective September 1, 1992, all laboratory testing sites (except as provided in 42 CFR 493.3(b)) must have either a CLIA certificate of waiver, certificate for provider-performed microscopy procedures, certificate of registration, certificate of compliance, or certificate of accreditation to legally perform clinical laboratory testing on specimens from individuals in the United States.

The Food and Drug Administration approves CLIA waived tests on a flow basis. The CMS identifies CLIA waived tests by providing an updated list of waived tests to the A/B MACs (A) and (B) on a quarterly basis via a Recurring Update Notification. To be recognized as a waived test, some CLIA waived tests have unique HCPCS procedure codes and some must have a QW modifier included with the HCPCS code.

Information regarding CLIA test complexity categorization can be found by searching the U.S. Food and Drug Administration website (www.fda.gov).

70.9 - HCPCS Subject To and Excluded From CLIA Edits

(Rev. 11463; Issued: 06-23-22; Effective: 07-25-22; Implementation: 07-25-22)

At this time, all claims submitted for laboratory tests subject to CLIA are edited at the CLIA certificate level. However, the HCPCS codes that are considered a laboratory test under CLIA change each year. The CMS identifies the new HCPCS (non-waived, non-provider-performed procedure) codes, including any modifiers that are subject to CLIA edits by providing an updated listing of these tests to the A/B MACs (A) and (B) on an annual basis via a Recurring Update Notification. A facility that submits a claim for any test mentioned in the HCPCS codes that are subject to CLIA edits list must have either a valid, current CLIA certificate of registration (certificate type 9), a CLIA certificate of compliance (certificate type 1), or a CLIA certificate of accreditation (certificate type 3).

Information regarding CLIA test complexity categorization can be found by searching the U.S. Food and Drug Administration website (www.fda.gov).

In addition, the CMS identifies the new HCPCS codes in the 80000 series that are excluded from CLIA edits by providing an updated listing of these tests to the A/B MACs (A) and (B) on an annual basis via a Recurring Update Notification. No CLIA certificate is required for a claim submitted for any test mentioned in the HCPCS codes in the 80000 series that are excluded from CLIA edits list.