

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-20 One-Time Notification</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 882</b>	<b>Date: April 22, 2011</b>
	<b>Change Request 7325</b>

**SUBJECT: Adjudication of Laboratory Tests that are Excluded from Clinical Laboratory Improvement Amendment (CLIA) Edits**

**I. SUMMARY OF CHANGES:** This Change Request instructs contractors to remove from CLIA editing all laboratory tests (and/or their components) that are included on the list of HCPCS codes in the 80000 series that are excluded from CLIA edits list.

**EFFECTIVE DATE: October 1, 2011**

**IMPLEMENTATION DATE: October 3, 2011**

*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.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N/A	

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

**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:**

**One-Time Notification**

*\*Unless otherwise specified, the effective date is the date of service.*

# Attachment – One-Time Notification

Pub. 100-20	Transmittal: 882	Date: April 22, 2011	Change Request: 7325
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**SUBJECT: Adjudication of Laboratory Tests that are Excluded from Clinical Laboratory Improvement Amendment (CLIA) Edits**

**Effective Date:** October 1, 2011

**Implementation Date:** October 3, 2011

## I. GENERAL INFORMATION

### A. Background:

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. All claims submitted for laboratory tests subject to CLIA are edited at the CLIA certificate level. However, the Healthcare Common Procedure Coding System (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 and excluded from CLIA edits by providing an updated listing of these tests to the Medicare contractors 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). 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.

For a list of the specific HCPCS codes subject to CLIA edits refer to <http://www.cms.hhs.gov/CLIA/downloads/Subject.to.CLIA.pdf>.

For a list of the specific HCPCS codes in the 80000 series that are excluded from CLIA edits refer to <http://www.cms.hhs.gov/CLIA/downloads/cpt4exc.pdf>.

### B. Policy:

Contractors are instructed to remove from CLIA editing all laboratory tests (and/or their components) included on the list of HCPCS codes in the 80000 series that are excluded from CLIA edits list. Contractors shall continue to receive Recurring Update Notifications that will identify new HCPCS codes in the 80000 series that are excluded from CLIA edits.

## II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an “X” in each applicable column)						
		A	D	F	C	R	S	O
		/	M	I	A	H	H	T
		B	E	R	H	M	A	I
							Shared-System Maintainers	OTHER

		M A C	M A C		R I E R	I	F I S S	M C S	V M S	C W F	
7325.1	For the purpose of this change request, contractors shall refer to the attached list of HCPCS codes in the 80000 series that are excluded from CLIA editing.	X			X					X	
7325.1.1	Contractors shall continue to receive notification of changes to the attached list via separate Recurring Update Notification.	X			X					X	
7325.2	Contractors shall not deny any HCPCS code on the list identified in 7325.1 for the lack of a CLIA number.	X			X						
7325.2.1	CWF shall update the HCPCS file as necessary to remove the indicator for CLIA editing for lab tests included on the list identified in BR 7325.1.									X	
7325.3	At the submitter's request, contractors shall reprocess any claim for dates of service on or after October 1, 2010 containing services on the list identified in 7325.1 that were previously denied for lack of a CLIA number.	X			X						
7325.4	Upon receipt of notification that a HCPCS code has been added to the list identified in BR 7325.1, contractors and CWF shall ensure that the requirements of this change request are followed with regard to the newly added code(s).	X			X					X	

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M A C	F I	C A R I E R	R H I	Shared-System Maintainers				OTH ER
						F I S S	M C S	V M S	C W F		
7325.5	<p>A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider</p>	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I  M A C	C A R I E R	R H I  S S	Shared-System Maintainers				OTH ER
							F I S S	M C S	V M S	C W F	
	community in billing and administering the Medicare program correctly.										

**IV. SUPPORTING INFORMATION**

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A**

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: For all other recommendations and supporting information, use this space: N/A**

**V. CONTACTS**

**Pre-Implementation Contact(s):** Felicia Rowe, [felicia.rowe@cms.hhs.gov](mailto:felicia.rowe@cms.hhs.gov) or 410-786-5655

**Post-Implementation Contact(s):** Contact your Contracting Officer’s Technical Representative (COTR) or Contractor Manager, as applicable.

**VI. FUNDING**

**Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**Section B: 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.

**ATTACHMENT**

## Tests (CPT-4 Codes) Excluded From CLIA Edits (Within the 80000 Series)

CPT only copyright 2009 American Medical Association. All rights reserved

CPT is a registered trademark of the American Medical Association.

Applicable FARS/DFARS Apply to Government Use.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

CPT	MOD	DESCRIPTION
80103		Tissue preparation for drug analysis
80500		Clinical pathology consultation; limited, without review of patient's history and medical records
80502		Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records
81050		Volume measurement for timed collection, each
82075		Alcohol (ethanol); breath
83013		Helicobacter pylori; breath test analysis for urease activity, non-radioactive isotope (e.g., C-13)
83014		Helicobacter pylori; drug administration
83987		pH; exhaled condensate - <b>Effective 1/1/2010</b>
84061		Phosphatase, acid; forensic examination
86077		Blood bank physician services; difficult cross match and/or evaluation of irregular antibody(s), interpretation and written report
86078		Blood bank physician services; investigation of transfusion reaction including suspicion of transmissible disease, interpretation and written report
86079		Blood bank physician services; authorization for deviation from standard blood banking procedures (eg, use of outdated blood, transfusion of Rh incompatible units), with written report
86485		Skin test; candida
86486		Skin test; unlisted antigen, each
86490		Skin test; coccidioidomycosis
86510		Skin test: histoplasmosis
86580		Skin test; tuberculosis, intradermal
86891		Autologous blood or component, collection processing and storage; intra-or postoperative salvage
86910		Blood typing, typing for paternity testing, per individual; ABO, Rh and MN
86911		Blood typing, for paternity testing, per individual; each additional antigen system
86923		Compatibility test each unit; electronic
86927		Fresh frozen plasma, thawing, each unit
86930		Frozen blood, each unit; freezing (includes preparation)
86931		Frozen blood, each unit; thawing
86932		Frozen blood, each unit; freezing (includes preparation) and thawing
86945		Irradiation of blood product, each unit
86950		Leukocyte transfusion
86960		Volume reduction of blood or blood products (eg, red blood cells or platelets), each unit
86965		Pooling of platelets or other blood products
86985		Splitting of blood or blood products, each unit
86999		Unlisted transfusion medicine procedure
87900		Infectious agent drug susceptibility phenotype prediction using regularly updated genotype bioinformatics
88000		Necropsy (autopsy), gross examination only; without CNS
88005		Necropsy (autopsy), gross examination only; with brain

CPT	MOD	DESCRIPTION
88007		Necropsy (autopsy), gross examination only; with brain and spinal cord
88012		Necropsy (autopsy), gross examination only; infant with brain
88014		Necropsy (autopsy), gross examination only; stillborn or newborn with brain
88016		Necropsy (autopsy), gross examination only; macerated stillborn
88020		Necropsy (autopsy), gross and microscopic; without CNS
88025		Necropsy (autopsy), gross and microscopic; with brain
88027		Necropsy (autopsy), gross and microscopic; with brain and spinal cord
88028		Necropsy (autopsy), gross and microscopic; infant with brain
88029		Necropsy (autopsy), gross and microscopic; stillborn or newborn with brain
88036		Necropsy (autopsy), limited, gross and/or microscopic; regional
88037		Necropsy (autopsy), limited, gross and/or microscopic; single organ
88040		Necropsy (autopsy); forensic examination
88045		Necropsy (autopsy); coroner's call
88099		Unlisted necropsy (autopsy) procedure
88125		Cytopathology, forensic (eg, sperm)
88240		Cryopreservation, freezing and storage of cells, each cell line
88241		Thawing and expansion of frozen cells, each aliquot
88304	TC	Level III -Surgical pathology, gross and microscopic examination
88305	TC	Level IV -Surgical pathology, gross and microscopic examination
88311		Decalcification procedure (List separately in addition to code for surgical pathology examination)
88312	TC	Special stains (list separately in addition to code for primary service); Group I for microorganisms (eg, Gridley, acid fast, methenamine silver), each
88313	TC	Special stains (list separately in addition to code for primary service); Group II, all other, (eg, iron, trichrome), except immunocytochemistry and immunoperoxidase stains, each
88314	TC	Special stains; histochemical staining with frozen section(s)
88329		Pathology consultation during surgery
88720		Bilirubin, total transcutaneous
88738		Hemoglobin (Hgb), quantitative, transcutaneous - <b>Effective 1/1/2010</b>
88740		Hemoglobin, quantitative, transcutaneous, per day; carboxyhemoglobin
88741		Hemoglobin, quantitative, transcutaneous, per day; methemoglobin
89049		Caffeine halothane contracture test (CHCT) for malignant hyperthermia susceptibility, including interpretation and report
89100		Duodenal intubation and aspiration; single specimen (eg, simple bile study or afferent loop culture) plus appropriate test procedure
89105		Duodenal intubation and aspiration; collection of multiple fractional specimens with pancreatic or gallbladder stimulation, single or double lumen tube
89130		Gastric intubation and aspiration, diagnostic, each specimen, for chemical analyses or cytopathology
89132		Gastric intubation and aspiration, diagnostic, each specimen, for chemical analyses or cytopathology; after stimulation
89135		Gastric intubation, aspiration, and fractional collections (eg, gastric secretory study); one hour
89136		Gastric intubation, aspiration, and fractional collections (eg, gastric secretory study); two hours
89140		Gastric intubation, aspiration, and fractional collections (eg, gastric secretory study); two hours including gastric stimulation (eg, histalog, pentagastrin)
89141		Gastric intubation, aspiration, and fractional collections (eg, gastric secretory study); three hours, including gastric stimulation
89220		Sputum, obtaining specimen, aerosol induced technique (separate procedure)

CPT	MOD	DESCRIPTION
89250		Culture and fertilization of oocyte(s)
89251		Culture and fertilization of oocyte(s); with co-culture of embryo
89253		Assisted embryo hatching, microtechniques (any method)
89254		Oocyte identification from follicular fluid
89255		Preparation of embryo for transfer (any method)
89257		Sperm identification from aspiration (other than seminal fluid)
89258		Cryopreservation; embryo
89259		Cryopreservation; sperm
89260		Sperm isolation; simple prep for insemination or diagnosis with semen analysis
89261		Sperm isolation; complex prep for insemination or diagnosis with semen analysis
89264		Sperm identification from testis tissue, fresh or cryopreserved
89268		Insemination of oocytes
89272		Extended culture of oocyte(s)/embryo(s), 4-7 days
89280		Assisted oocyte fertilization, microtechnique; less than or equal to 10 oocytes
89281		Assisted oocyte fertilization, microtechnique; greater than 10 oocytes
89290		Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89291		Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); greater than 5 embryos
89335		Cryopreservation, reproductive tissue, testicular
89342		Storage, (per year); embryo(s)
89343		Storage, (per year); sperm/semen
89344		Storage, (per year); reproductive tissue, testicular/ovarian
89346		Storage, (per year); oocyte(s)
89352		Thawing of cryopreserved; embryo(s)
89353		Thawing of cryopreserved; sperm/semen, each aliquot
89354		Thawing of cryopreserved; reproductive tissue, testicular/ovarian
89356		Thawing of cryopreserved; oocytes, each aliquot
89398		Unlisted reproductive medicine laboratory procedure - <b>Effective 1/1/2010</b>