CMS Guidance Document	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Executive Guidance Number 0628	**Date: December 3, 2008**
Planned Web Site Address http://www.cms.hhs.gov/manuals/	**Release planned: 12/17/08**

PROGRAM AREA: Clinical Laboratory Fee Schedule

SUBJECT: Calendar Year (CY) 2009 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

APPLIES TO: Clinical Diagnostic Laboratories

I. SUMMARY OF DOCUMENT: This Recurring Update Notification (RUN) provides instructions for the CY 2009 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. This RUN applies to Chapter 16, Section 50.5.3.

NEW / REVISED MATERIAL
EFFECTIVE DATE: January 1, 2009
IMPLEMENTATION DATE: January 5, 2009

II. CHANGES IN POLICY INSTRUCTIONS: (If not applicable, indicate N/A)
STATUS: R=REVISED, N=NEW, D=DELETED.

Status	**CHAPTER/SECTION/SUBSECTION/TITLE**
N/A	

III. CLEARANCES:

Clearance & Point of Contact (POC)	Name/Telephone/Component
Senior Official Clearance	Jeffrey Rich, M.D., Director, CMM, (410) 786-4164
Agency POC	Anne Tayloe, CMM/HAPG/DAS, (410) 786-5456

IV. TYPE:

	Audit Guide
	Change Request
	HPMS
	Joint Signature Memorandum/Technical Director Letter
	Manual Transmittal/Non-Change Request
	State Medicaid Director Letters
	Other

V. STATUTORY OR REGULATORY AUTHORITY: Section 1833(h)(2)(A)(i) of the Social Security Act, as amended by Section 145(b) of the Medicare Improvements for Patients and Providers Act of 2008

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal:	Date:	Change Request: 6070

SUBJECT: Calendar Year (CY) 2009 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: January 1, 2009

IMPLEMENTATION DATE: January 5, 2009

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification provides instructions for the CY 2009 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment.

B. Policy:

Update to Fees

In accordance with Section 1833(h)(2)(A)(i) of the Social Security Act (the Act), as amended by Section 145(b) of the Medicare Improvements for Patients and Providers Act of 2008, the annual update to the local clinical laboratory fees for CY 2009 is 4.5 percent. Section 1833(a)(1)(D) of the Act provides that payment for a clinical laboratory test is the lesser of the actual charge billed for the test, the local fee, or the national limitation amount (NLA). For a cervical or vaginal smear test (pap smear), Section 1833(h)(7) of the Act requires payment to be the lesser of the local fee or the NLA, but not less than a national minimum payment amount (described below). However, for a cervical or vaginal smear test (pap smear), payment may also not exceed the actual charge. The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.

National Minimum Payment Amounts

For a cervical or vaginal smear test (pap smear), Section 1833(h)(7) of the Act requires payment to be the lesser of the local fee or the NLA, but not less than a national minimum payment amount. Also, payment may not exceed the actual charge. The CY 2009 national minimum payment amount is $15.42 ($14.76 plus 4.5 percent update for CY 2009). The affected codes for the national minimum payment amount are 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, and P3000.

National Limitation Amounts (Maximum)

For tests for which NLAs were established before January 1, 2001, the NLA is 74 percent of the median of the local fees. For tests for which the NLAs are first established on or after January 1, 2001, the NLA is 100 percent of the median of the local fees in accordance with Section 1833(h)(4)(B)(viii) of the Act.

Access to Data File

The CY 2009 clinical laboratory fee schedule data file should be retrieved electronically through CMS' mainframe telecommunications system. Carriers should retrieve the data file on or after November 3, 2008. Intermediaries should retrieve the data file on or after November 17, 2008. Internet access to the CY 2009

clinical laboratory fee schedule data file should be available after November 17, 2008, at http://www.cms.hhs.gov/ClinicalLabFeeSched. Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, should use the Internet to retrieve the CY 2009 clinical laboratory fee schedule. It will be available in multiple formats: Excel, text, and comma delimited.

Data File Format

For each test code, if your system retains only the pricing amount, load the data from the field named "60% Pricing Amt." For each test code, if your system has been developed to retain the local fee and the NLA, you may load the data from the fields named "60% Local Fee Amt" and "60% Natl Limit Amt" to determine payment. For test codes for cervical or vaginal smears (pap smears), you should load the data from the field named "60% Pricing Amt" which reflects the lower of the local fee or the NLA, but not less than the national minimum payment amount. Fiscal intermediaries should use the field "62% Pricing Amt" for payment to qualified laboratories of sole community hospitals.

Public Comments

On July 14, 2008, CMS hosted a public meeting to solicit input on the payment relationship between CY 2008 codes and new CY 2009 Current Procedural Terminology (CPT) codes. Notice of the meeting was published in the Federal Register on May 23, 2008, and on the CMS web site approximately June 16, 2008. Recommendations were received from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted a summary of the meeting and the tentative payment determinations on the web site at http://www.cms.hhs.gov/ClinicalLabFeeSched. Additional written comments from the public were accepted until October 10, 2008. We posted a summary of public comments along with preliminary determinations on the website and will post our final payment determinations on said website.

Pricing Information

The CY 2009 clinical laboratory fee schedule includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). The fees have been established in accordance with Section 1833(h)(4)(B) of the Act.

For dates of service from July 1, 2008, through December 31, 2009, the fee for clinical laboratory travel code P9603 is $1.035 per mile (round to $1.04 if necessary) and the fee for clinical laboratory travel code P9604 is $10.35 per flat rate trip basis (Change Request 6195, Transmittal 1584, dated September 5, 2008, incorrectly updated the P9604 dollar figure, so we are correcting it here as of July 1, 2008). The clinical laboratory travel codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient. If there is a revision to the standard mileage rate for CY 2009, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2009 clinical laboratory fee schedule also includes codes that have a "QW" modifier to both identify codes and determine payment for tests performed by a laboratory registered with only a certificate of waiver under the Clinical Laboratory Improvement Amendments (CLIA).

Organ or Disease Oriented Panel Codes

Similar to prior years, the CY 2009 pricing amounts for certain organ or disease panel codes and evocative/suppression test codes were derived by summing the lower of the clinical laboratory fee schedule amount or the NLA for each individual test code included in the panel code. The NLA field on the data file is zero-filled.

Mapping Information

New code 83876 is priced at the same rate as code 83520.

New code 83951 is priced by adding the rates for code 83950.

New code 85397 is priced at the same rate as code 85245.

New code 87905 is priced by subtracting the rate for code 87176 from the rate for code 82657.

New code 88720 is priced at the same rate as code 88400.

New code 88740 is priced at the same rate as code 88400.

New code 88741 is priced at the same rate as code 88400.

Code 88400 is deleted beginning CY 2009.

Healthcare Common Procedure Coding System (HCPCS) Code G0394 is deleted beginning CY 2009.

For CY 2009, there are no new test codes to be gap filled.

Laboratory Costs Subject to Reasonable Charge Payment in CY 2009

For outpatients, the following codes are paid under a reasonable charge basis. In accordance with 42 CFR 405.502 through 42 CFR 405.508, the reasonable charge may not exceed the lowest of the actual charge or the customary or prevailing charge for the previous 12-month period ending June 30, updated by the inflation-indexed update. The inflation-indexed update is calculated using the change in the applicable Consumer Price Index for the 12-month period ending June 30 of each year as prescribed by Section 1842(b)(3) of the Act and 42 CFR 405.509(b)(1). Further, Section 145 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) adjusted the inflation-indexed update by -0.5 percent. Therefore, the inflation-indexed update for CY 2009 is 4.5 percent.

Manual instructions for determining the reasonable charge payment can be found in Chapter 23, Section 80 through 80.8. If there is insufficient charge data for a code, the instructions permit considering charges for other similar services and price lists.

When these services are performed for independent dialysis facility patients, Chapter 8, Section 60.3 instructs that the reasonable charge basis applies. However, when these services are performed for hospital-based renal dialysis facility patients, payment is made on a reasonable cost basis. Also, when these services are performed for hospital outpatients, payment is made under the hospital outpatient prospective payment system (OPPS).

Blood Products

P9010
P9011
P9012
P9016
P9017
P9019
P9020
P9021

P9022
P9023
P9031
P9032
P9033
P9034
P9035
P9036
P9037
P9038
P9039
P9040
P9044
P9050
P9051
P9052
P9053
P9054
P9055
P9056
P9057
P9058
P9059
P9060

Also, the following codes should be applied to the blood deductible as instructed in the Medicare General Information, Eligibility and Entitlement Manual, Publication 100-01, Chapter 3, Section 20.5 through 20.5.4 (formerly the Medicare Carriers Manual (MCM) 2455):

P9010
P9016
P9021
P9022
P9038
P9039
P9040
P9051
P9054
P9056
P9057
P9058

NOTE: Biologic products not paid on a cost or prospective payment basis are paid based on Section 1842(o) of the Act. The payment limits based on Section 1842(o), including the payment limits for codes P9041, P9043, P9045, P9046, P9047, P9048, should be obtained from the Medicare Part B drug pricing files.

Transfusion Medicine

86850
86860
86870
86880

86885
86886
86890
86891
86900
86901
86903
86904
86905
86906
86920
86921
86922
86923
86927
86930
86931
86932
86945
86950
86960
86965
86970
86971
86972
86975
86976
86977
86978
86985
G0267

Reproductive Medicine Procedures

89250
89251
89253
89254
89255
89257
89258
89259
89260
89261
89264
89268
89272
89280
89281
89290
89291
89335

89342
89343
89344
89346
89352
89353
89354
89356

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6070.1	Carriers shall retrieve the CY 2009 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY09.V1103) from the CMS mainframe on or after November 3, 2008. Carriers shall notify of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., carrier name and number).	X			X			X			
6070.2	Fiscal intermediaries shall retrieve the CY 2008 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY09.V1117.FI) from the CMS mainframe on or after November 17, 2008. Fiscal intermediaries shall notify of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., fiscal intermediary name and number).	X		X			X				
6070.3	Carriers shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis. Determining customary and prevailing charges should use data from July 1, 2007 through June 30, 2008, updated by the inflation-index update for year CY 2009 of 4.5 percent. Fiscal intermediaries shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients.	X		X	X		X	X			
6070.4	Contractors shall establish the fee for laboratory travel code P9603 at $1.035 per mile and for code P9604 at $10.35 per flat rate trip basis effective for dates of service on or after July 1, 2008. If there is a revision to	X		X	X			X			

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	the standard mileage rate for CY 2009, CMS will issue a separate instruction on the clinical laboratory travel fees.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6070.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. 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 community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

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

X-Ref Requirement Number	Recommendations or other supporting information:
N/A	N/A

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk at glenn.mcguirk@cms.hhs.gov

Post-Implementation Contact(s): Glenn McGuirk at glenn.mcguirk@cms.hhs.gov

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHIs)* use only one of the following statements:

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),* use the following statement:

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.