

<b>CMS Manual System</b>	Department of Health & Human Services (DHHS)
<b>Pub 100-04 Medicare Claims Processing</b>	Centers for Medicare & Medicaid Services (CMS)
<b>Transmittal 1660</b>	<b>Date: DECEMBER 31, 2008</b>
	<b>Change Request 6070</b>

**NOTE: Transmittal 1651, dated December 19, 2008 is being rescinded and replaced by Transmittal 1660, dated December 31, 2008. We are resending CR 6070 due to revisions in the Recurring Update Notification. The changes are the annual update to payments made using the clinical laboratory fee schedule for CY 2009 is 4.5 percent; payments made on a reasonable charge basis for all other laboratory services is updated by 5.0 percent. Also the percentage in Business Requirement 6070.3 is changed from 4.5 percent to 5.0 percent. All other information in this RUN remains the same.**

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

**I. SUMMARY OF CHANGES:** 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

*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:**

**SECTION A: For Fiscal Intermediaries and 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.

#### **IV. ATTACHMENTS:**

##### **Recurring Update Notification**

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

# Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1660	Date: December 31, 2008	Change Request: 6070
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**NOTE: Transmittal 1651, dated December 19, 2008 is being rescinded and replaced by Transmittal 1660, dated December 31, 2008. We are resending CR 6070 due to revisions in the Recurring Update Notification. The changes are the annual update to payments made using the clinical laboratory fee schedule for CY 2009 is 4.5 percent; payments made on a reasonable charge basis for all other laboratory services is updated by 5.0 percent. Also the percentage in Business Requirement 6070.3 is changed from 4.5 percent to 5.0 percent. All other information in this RUN remains the same.**

**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 (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.

## **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 payments made using the clinical laboratory fee schedule for CY 2009 is 4.5 percent; payments made on a reasonable charge basis for all other laboratory services is updated by 5.0 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, 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 Publication 100-04, Medicare Claims Processing Manual, 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, Publication 100-04, Medicare Claims Processing Manual, 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 Publication 100-01, Medicare General Information, Eligibility and Entitlement Manual, Chapter 3, Section 20.5 through 20.54 (formerly 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*

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*Reproductive Medicine Procedures*

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## II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
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 <a href="mailto:price_file_receipt@cms.hhs.gov">price_file_receipt@cms.hhs.gov</a> 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 <a href="mailto:price_file_receipt@cms.hhs.gov">price_file_receipt@cms.hhs.gov</a> 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	X		X	X		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	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	the inflation-index update for year CY 2009 of 5.0 percent. Fiscal intermediaries shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients.										
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 the standard mileage rate for CY 2009, CMS will issue a separate instruction on the clinical laboratory travel fees.	X		X	X			X			

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6070.5	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. 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:**

<b>X-Ref Requirement Number</b>	<b>Recommendations or other supporting information:</b>
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X-Ref Requirement Number	Recommendations or other supporting information:
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.