CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1884	**Date: December 23, 2009**
	Change Request 6657

SUBJECT: Calendar Year (CY) 2010 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 2010 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. This Recurring Update Notification (RUN) applies to chapter 16, section 20.2.

New / Revised Material
Effective Date: January 1, 2010
Implementation Date: January 4, 2010

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
D	16/50/5.3/Recurring Update Notification Containing New Pricing File Names and Retrieval Dates for 2006
R	16/20/2/Annual Fee Schedule Updates

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:

Manual Instruction

Recurring Update Notification

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1884	Date: December 23, 2009	Change Request: 6657

SUBJECT: Calendar Year (CY) 2010 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

Effective Date: January 1, 2010
Implementation Date: January 4, 2010

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the CY 2010 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 628 of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003, the annual update to the local clinical laboratory fees for CY 2010 is (-1.4) percent. Further, Section 145 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) adjusted the annual update by (-0.5) percent through CY 2013. Therefore, the annual update to payments made using the Clinical Laboratory Fee Schedule (CLFS) for CY 2010 is (-1.9) percent. The annual update to payments made on a reasonable charge basis for all other laboratory services for CY 2010 is 0 percent (See 42 CFR 405.509(b)(1)). 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 2010 national minimum payment amount is $15.13 ($15.42 plus (-1.9) percent update for CY 2010). 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 2010 clinical laboratory fee schedule data file shall be retrieved electronically through CMS' mainframe telecommunications system. Carriers shall retrieve the data file on or after November 9, 2009. Intermediaries shall retrieve the data file on or after November 16, 2009. Internet access to the CY 2010 clinical laboratory fee schedule data file shall be available after November 16, 2009, 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, shall use the Internet to retrieve the CY 2010 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, 2009, CMS hosted a public meeting to solicit input on the payment relationship between CY 2009 codes and new CY 2010 Current Procedural Terminology (CPT) codes. Notice of the meeting was published in the Federal Register on May 22, 2009, and on the CMS Web site approximately June 15, 2009. 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 September 18, 2009. CMS has posted a summary of the public comments and the rationale for the final payment determinations on the CMS Web site.

Pricing Information

The CY 2010 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 beginning January 1, 2009, the fee for clinical laboratory travel code P9603 is $1.00 per mile and the fee for clinical laboratory travel code P9604 is $10.00 per flat rate trip basis. 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 2010, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2010 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 having only a certificate of waiver under the Clinical Laboratory Improvement Amendments (CLIA).

Organ or Disease Oriented Panel Codes

Similar to prior years, the CY 2010 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 83987 is priced at the sum of the rates of codes 82800 and 87015.

New code 84145 is priced at the same rate as code 84146.

New code 84431 is priced at the same rate as code 83520.

New code 86305 is priced at the same rate as code 86316.

New code 86352 is priced at the sum of the rates of codes 86353 and 82397.

New code 86780 is priced at the same rate as code 86781.

New code 86825 is priced at three times the rate of code 86356.

New code 86826 is priced at the same rate as code 86356.

New code 87150 is priced at the same rate as code 87798.

New code 87153 is priced at the sum of the rates of codes 83891, 83898, 83904, 83912, and half of code 87900.

New code 87493 is priced at the same rate as code 87798.

New code 88738 is priced at the same rate as code 88740.

New code 80069QW is priced at the same rate as code 80069 beginning December 4, 2008.

New code 82040QW is priced at the same rate as code 82040 beginning January 1, 2009.

New code 82043QW is priced at the same rate as code 82043 beginning October 1, 2009.

New code 82550QW is priced at the same rate as code 82550 beginning December 4, 2008.

New code 87905QW is priced at the same rate at code 87905 beginning January 1, 2009.

Code 83876 is priced at the same rate as code 83880.

Healthcare Common Procedure Coding System (HCPCS) Code G0430 is priced at the same rate as code 80100.

Healthcare Common Procedure Coding System (HCPCS) Code G0431 is priced at the same rate as code 80101.

Code 82307 is deleted beginning January 1, 2010.

Code 82042QW is deleted beginning July 1, 2009.

Code 83520QW is deleted beginning October 1, 2009.

Code 86781 is deleted beginning January 1, 2010.

For CY 2010, there are no new test codes to be gapfilled.

Laboratory Costs Subject to Reasonable Charge Payment in CY 2010

For outpatients, the following codes are paid under a reasonable charge basis (See Section 1842(b)(3) of the Act). 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 set forth in 42 CFR 405.509(b)(1). The inflation-indexed update for CY 2010 is 0 percent.

Manual instructions for determining the reasonable charge payment can be found in Pub. 100-04, Medicare Claims Processing Manual, chapter 23, section 80 through section 80.8. If there is insufficient charge data for a code, the instructions permit considering charges for other similar services and price lists.

When services described by the HCPCS in the following list are performed for independent dialysis facility patients, Pub. 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, payment for the following codes should be applied to the blood deductible as instructed in Pub. 100-01, Medicare General Information, Eligibility and Entitlement Manual, chapter 3, cection 20.5 through 20.5.4:

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

Reproductive Medicine Procedures

89250
89251
89253
89254
89255
89257
89258
89259
89260
89261
89264
89268
89272
89280
89281
89290
89291
89335
89342
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89344
89346
89352
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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	
6657.1	Carriers shall retrieve the CY 2010 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY10.V1109C) from the CMS mainframe on or after November 9, 2009.	X			X						
6657.1.1	Carriers shall notify CMS 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						
6657.2	Intermediaries shall retrieve the CY 2010 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY10.V1116C.FI) from the CMS mainframe on or after November 16, 2009.	X		X							
6657.2.1	Intermediaries shall notify CMS 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							
6657.3	Contractors shall manually remove Code 82042QW from the Clinical Laboratory Fee Schedule (CLFS) beginning July 1, 2009.	X			X						
6657.3.1	Contractors shall manually remove Code 83520QW from the Clinical Laboratory Fee Schedule (CLFS) beginning October 1, 2009.	X			X						
6657.4	CMS shall establish and/or retain two different pricing localities to reflect the Clinical Laboratory Fee Schedule (CLFS) amounts that are paid for East and West Kansas. Locality 15 shall reflect the East Kansas CLFS pricing and Locality 12 shall reflect the West Kansas CLFS pricing.	X			X						
6657.4.1	CMS shall use locality codes of 15 and 12 for East and West Kansas respectively on the CLFS pricing files.	X			X						
6657.4.2	CMS shall use State code EK for East Kansas and WK for West Kansas.	X			X						
6657.5	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X		X	X						
6657.6	Carriers shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.	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	
6657.7	Carriers shall determine customary and prevailing charges by using data from July 1, 2008 through June 30, 2009, updated by the inflation-index update for year CY 2010 of 0 percent.	X			X						
6657.8	Intermediaries shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients.	X		X							
6657.9	Contractors shall establish the fee for laboratory travel code P9603 at $1.00 per mile and for code P9604 at $10.00 per flat rate trip basis effective for dates of service on or after January 1, 2009. If there is a revision to the standard mileage rate for CY 2010, CMS will issue a separate instruction on the clinical laboratory travel fees.	X		X	X						

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	
6657.10	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 1 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	

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)*:

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.

20.2 - Annual Fee Schedule Updates

(Rev.1884, Issued: 12-23-09, Effective: 01-01-10, Implementation: 01-04-10)

The CMS adjusts *t*he fee schedule amounts annually to reflect changes in the Consumer Price Index for all urban consumers *(CPI-U)* (U.S. city average), *unless another update is* specified by legislation. *The CMS communicates this information via an annual recurring update notification (RUN).* The CMS also determines, publishes for contractor use, and places on its Web site, coding and pricing changes. *This information is updated on an annual basis*.