CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2106	**Date: November 24, 2010**
	Change Request 6991

This transmittal is being re-issued on December 14, 2010 to insert the Revision number, date issued, effective and implementation dates in the manual instruction, which were erroneously omitted during the original communication. The transmittal number, date issued and all other information remains the same.

SUBJECT: Calendar Year (CY) 2011 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 2011 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment.

EFFECTIVE DATE: January 1, 2011
IMPLEMENTATION DATE: January 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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	16/20/2 - Annual Fee Schedule Updates

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs):
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:
Manual Instruction

Recurring Update Notification

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 2106	Date: November 24, 2010	Change Request: 6991

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SUBJECT: Calendar Year (CY) 2011 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

Effective Date: January 1, 2011

Implementation Date: January 3, 2011

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the CY 2011 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 also effectuates a manual update of Chapter 16, Section 20.2, to incorporate additional information about the annual update.

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, and further amended by Section 3401 of the Patient Protection and Affordable Care Act (PPACA) of 2010, the annual update to the local clinical laboratory fees for CY 2011 is -1.75 percent. The annual update to local clinical laboratory fees for CY 2011 reflects an additional multi-factor productivity adjustment and a -1.75 percentage point reduction as described by the PPACA legislation. The annual update to payments made on a reasonable charge basis for all other laboratory services for CY 2011 is 1.1 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 2011 national minimum payment amount is $14.87 ($15.13 plus (-1.75) percent update for CY 2011). 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, 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 2011 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 12, 2010. Intermediaries shall retrieve the data file on or after November 19, 2010. Internet access to the CY 2011 clinical laboratory fee schedule data file shall be available after November 19, 2010, 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 2011 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 22, 2010, CMS hosted a public meeting to solicit input on the payment relationship between CY 2010 codes and new CY 2011 Current Procedural Terminology (CPT) codes. Notice of the meeting was published in the Federal Register on May 28, 2010, and on the CMS web site approximately June 15, 2010. 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 29, 2010. 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 2011 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.

The fees for clinical laboratory travel codes P9603 and P9604 are updated on an annual 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 2011, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2011 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 2011 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 82930 is priced at the same rate as code 82926.

New code 83861 is priced at the same rate as code 83909.

New code 84112 is priced at the same rate as code 82731.

New code 85598 is priced at the same rate as code 85597.

New code 86481 is priced at the same rate as code 86480.

New code 86902 is priced at the same rate as code 86905.

New code 87501 is priced at the sum of the rates of codes 87521 and 83902.

New code 87502 is priced at the sum of the rates of codes 87801 and 83902.

New code 87503 is priced at the sum of the rates of codes 83901 and 83896.

New code 87906 is priced at half of code 87901.

Healthcare Common Procedure Coding System (HCPCS) Code G0434 is priced at the same rate as code G0430.

Healthcare Common Procedure Coding System (HCPCS) Code G9143 is priced at the sum of the rates of codes 83891, 83900, 83901, 83912, three times the rate of code 83896, and three times the rate of code 83908. A two-character modifier indicates that this test's use is limited to within a Coverage with Evidence Development (CED) study.

Healthcare Common Procedure Coding System (HCPCS) Code G0432 is priced at the same rate as code 86703.

Healthcare Common Procedure Coding System (HCPCS) Code G0433 is priced at the same rate as code 86703.

Healthcare Common Procedure Coding System (HCPCS) Code G0435 is priced at the same rate as code 87804.

Reconsidered code 84145 is priced at the same rate as code 82308.

Reconsidered code 84431 is priced at the same rate as code 84443.

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

Healthcare Common Procedure Coding System (HCPCS) Code G0430 is deleted beginning January 1, 2011.

Healthcare Common Procedure Coding System (HCPCS) Code G0431 is priced at five times the rate of HCPCS Code G0430.

Code 84155QW is priced at the same rate as code 84155 beginning January 1, 2010.

Code 87809QW is priced at the same rate as code 87809 beginning January 1, 2008.

For CY 2011, there are no new test codes that need to be gapfilled.

Laboratory Costs Subject to Reasonable Charge Payment in CY 2011

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 2011 is 1.1 percent.

Manual instructions for determining the reasonable charge payment can be found in Publication 100-4, Medicare Claims Processing Manual, Chapter 23, Section 80 through 80.8. If there is sufficient 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, 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, payment for 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 20.5.4:

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, and 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
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86985

Reproductive Medicine Procedures

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89280
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II. BUSINESS REQUIREMENTS TABLE

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

		MAC	MAC		RIER	I	FISS	MCS	VMS	CWF	
6991.1	Carriers shall retrieve the CY 2011 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY11.V1112) from the CMS mainframe on or after November 12, 2010.	X			X						
6991.1.1	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						
6991.2	Intermediaries shall retrieve the CY 2011 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY11.V1119.FI) from the CMS mainframe on or after November 19, 2010.	X		X			X				
6991.2.1	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			X				
6991.3	CWF shall remove code P9011 from existing blood deductible edits.									X	
6991.4	Contractors shall manually include Code 84155QW in the Clinical Laboratory Fee Schedule (CLFS) pricing files beginning January 1, 2010.	X			X						
6991.4.1	Contractors shall manually include Code 87809QW in the Clinical Laboratory Fee Schedule (CLFS) pricing files beginning January 1, 2008.	X			X						
6991.5	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						
6991.6	Carriers shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.	X			X						
6991.7	Carriers shall determine customary and prevailing charges by using data from July 1, 2009 through June 30, 2010, updated by the inflation-index update for year CY 2011 of 1.1 percent.	X			X						
6991.8	Intermediaries shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients.	X		X							
6991.9	If there is a revision to the standard mileage rate for CY 2011, CMS will issue a separate instruction on the clinical laboratory travel fees.										CMS

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	
6991.10	Contractors shall be apprised that the Medicare indicator for new CPT Code 80104 is "I" to indicate "Not Valid for Medicare Purposes. Medicare uses another code for reporting of, and payment for, these services." This indicator change is effective January 1, 2011.	X		X	X						
6991.11	Contractors shall be apprised that the Medicare indicator for CPT Code 80100 is changed to "I" to indicate "Not Valid for Medicare Purposes. Medicare uses another code for reporting of, and payment for, these services." This indicator change is effective January 1, 2011.	X		X	X						
6991.12	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

Section B: For all other recommendations and supporting information, use this space:

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), Regional Home Health Intermediaries (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)*:

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. 2106, Issued: 11-24-10, Effective: 01-01-11, Implementation: 01-03-11)

The CMS adjusts the fee schedule amounts annually to reflect changes in the Consumer Price Index for all urban consumers (CPI-U) (U.S. city average) *and the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity*, unless *alternative* update*s are* 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.