CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 750

Department of Health & Human Services (DHHS)

Center for Medicare & Medicaid Services (CMS)

Date: NOVEMBER 10, 2005

Change Request 4144

SUBJECT: 2006 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

I. SUMMARY OF CHANGES: This change will inform contractors of updates to the Medicare Part B clinical laboratory fees and codes.

NEW/REVISED MATERIAL

EFFECTIVE DATE: January 1, 2006

IMPLEMENTATION DATE: January 3, 2006

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
N/A	

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Recurring Update Notification

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 750	Date: November 10, 2005	Change Request 4144

SUBJECT: 2006 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification provides instructions for the calendar year 2006 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 §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 2006 is 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), §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), §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 2006 national minimum payment amount is $14.76 ($14.76 plus 0 percent update for 2006). 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 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 §1833(h)(4)(B)(viii) of the Act.

Access to Data File

The 2006 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, 2005. Intermediaries should retrieve the data file on or after November 18, 2005.

Internet access to the 2006 clinical laboratory fee schedule data file should be available after November 18, 2005, at www.cms.hhs.gov/suppliers/clinlab. Medicaid State agencies, the Indian Health Service, the United Mine Workers, Railroad Retirement Board, and other interested parties should use the Internet to retrieve the 2006 clinical laboratory fee schedule. It will be available in multiple formats: Excel, text, and comma delimited.

Data File Format

Attachment A depicts the record layout of the 2006 clinical laboratory fee schedule data file for carriers. Attachment B depicts the record layout of the 2006 clinical laboratory fee schedule data file for intermediaries. 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. Intermediaries should use the field '62% Pricing Amt' for payment to qualified laboratories of sole community hospitals.

Attachment C lists new and deleted codes for the 2006 clinical laboratory fee schedule. The data file will include the new codes listed in Attachment C. Deleted codes will not be included in the data file. In compliance with the Health Insurance Portability and Accountability Act, CMS instructed the elimination of a 3-month grace period for discontinued codes in Change Request 3093 issued February 6, 2004.

Public Comments

On July 18, 2005, CMS hosted a public meeting to solicit input on the payment relationship between 2005 codes and new 2006 Current Procedural Terminology codes. Notice of the meeting was published in the **Federal Register** on May 27, 2005 and on the CMS Web site on June 20, 2005. 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 www.cms.hhs.gov/suppliers/clinlab. Additional written comments from the public were accepted until September 23, 2005.

Comments after the release of the 2006 laboratory fee schedule can be submitted to the following address so that CMS may consider them for the development of the 2007 laboratory fee schedule. A comment should be in written format and include clinical, coding, and costing information. To make it possible for CMS and its contractors to meet a January 3, 2007 implementation date, comments must be submitted before August 1, 2006.

Centers for Medicare & Medicaid Services (CMS)
Center for Medicare Management
Division of Ambulatory Services
Mailstop: C4-07-07
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Pricing Information

Mapping Information for New and Revised Codes The 2006 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 §1833(h)(4)(B) of the Act.

For dates of service on or after September 1, 2005, the fee for clinical laboratory travel code P9603 is $0.935 per mile and for code P9604 is $9.35 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. The standard mileage rate for transportation costs was increased by the Federal Government's Treasury Department to 48.5 cents a mile effective September 1, 2005 and this increase is incorporated into the fees for travel codes P9603 and P9604. The update to the standard mile rate occurred earlier than the January 1st update of prior years. If there is a revision to the standard mileage rate for calendar year 2006, CMS will issue a separate instruction to contractors on the clinical laboratory travel fees.

The 2006 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.

Organ or Disease Oriented Panel Codes

Similar to prior years, the 2006 pricing amounts for certain organ or disease panel codes and evocative/suppression test codes were derived by summing the lower of the fee schedule amount or the NLA for each individual test code included in the panel code. The national limitation amount field on the data file is zero-filled.

New code 80195 is priced at the same rate as code 80197.

New code 82271 is priced at the same rate as code 82270.

New code 82271QW is priced at the same rate as code 82270.

New code 82272 is priced at the same rate as code 82270.

New code 82272QW is priced at the same rate as code 82270.

New code 83631 is priced at the sum of the rates of codes 83520 and 87015.

New code 83695 is priced at the same rate as code 83520.

New code 83700 is priced at the same rate as deleted code 83715.

New code 83701 is priced at the same rate as deleted code 83716.

New code 83704 is priced at the sum of the rates of deleted code 83716 and code 85004.

New code 83721QW is priced at the same rate as code 83721.

New code 83880QW is priced at the same rate as code 83880.

New code 83900 is priced at the same rate as code 83901 (x2).

New code 83907 is priced at the same rate as code 87015 (x2).

New code 83908 is priced at the same rate as code 83898.

New code 83909 is priced at the same rate as code 83904.

New code 83914 is priced at the same rate as code 83904.

New code 85576QW is priced at the same rate as code 85576.

New code 86200 is priced at the same rate as code 83520.

New code 86355 is priced at the same rate as deleted code 86064.

New code 86357 is priced at the same rate as deleted code 86379.

New code 86367 is priced at the same rate as deleted code 86587.

New code 86480 is priced at the sum of the rates of codes 86353 and 83520.

New code 86586 is priced at the same rate as deleted code 86587.

New code 86703QW is priced at the same rate as code 86703.

New code 87209 is priced at the same rate as code 87207 (x3).

New code 87807QW is priced at the same rate as code 87807.

New code 87900 is priced at the same rate as code 87904 (x5).

Gap-fill Payments for New Laboratory Tests

In accordance with §531(b) of the Benefits Improvement and Protection Act of 2000, CMS solicits public comments on determining payment amounts for new laboratory tests. As described earlier, CMS hosts an annual public meeting to allow parties the opportunity to provide input to the payment determination process. The CMS employs one of two approaches to establishing payment amounts for new laboratory test codes, crosswalking and gap-filling. After considering public input regarding the new test codes, CMS determines which approach is most appropriate for each new test code. In determining gap-fill amounts, the sources of information carriers should examine, if available, include: charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. Carriers may consider other sources of information as appropriate, including clinical studies and information provided by clinicians practicing in the area, manufacturers, or other interested parties.

After determining a gap-fill amount, a carrier may consider if a least costly alternative (LCA) to a new test exists (see Pub. 100-08, Program Integrity Manual, §13.5.4.). The method of implementing a LCA is through the Local Medical Review Policy (LMRP) process. If a carrier determines LCA, the carrier may adopt the payment amount of the LCA test code as the gap-fill amount for the new test code. However in this case, the carrier must report two payment amounts, the gap-fill amount prior to determination of LCA and the payment amount that the carrier has determined to be LCA.

For 2006, the gap-fill payment determinations are effective for services rendered from January 1, 2006 to December 31, 2006. Carriers shall establish gap-fill amounts and provide this information to their Regional Office (RO) on or before March 31, 2006. Carriers may revise the gap-fill amounts and should report revisions to their RO no later than September 1, 2006. The local fees will be established based on the gap-fill amounts reported as of September 1, 2006, and CMS will set the NLA for the new test code at 100 percent of the median of all local fees.

Carriers should also communicate the gap-fill amounts to corresponding intermediaries. Carriers should receive assistance from RO staff to facilitate communication of the gap-fill amounts to intermediaries. The list of codes which carriers are required to gap-fill for 2006 can be found in Attachment C. Attachment D contains the record layout for the submittal of the 2006 gap-fill amounts.

Laboratory Costs Subject to Reasonable Charge Payment in 2006

For outpatients, the following codes are paid under a reasonable charge basis. In accordance with 42 CFR 405.502 – 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 §1842(b)(3) of the Act and 42 CFR 405.509(b)(1). The inflation-indexed update for year 2006 is 2.5 percent.

Manual instructions for determining the reasonable charge payment can be found in Pub. 100-04, Medicare Claims Processing Manual, Chapter 23, §80-80.8. 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, Pub. 100-04, Medicare Claims Processing Manual, Chapter 8, §60.3 instructs 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).

Transmittal 496, Billing for Blood and Blood Products (Change Request (CR) 3681) issued March 4, 2005 provided instructions and established a new HCPCS modifier BL *Special Acquisition of Blood and Blood Products* to better specify the blood product charge in the hospital outpatient setting. Because blood product services can also be performed in physician offices, independent laboratories, renal dialysis facilities, and other outpatient settings, contractors and shared system maintainers shall update their files to accept the modifier BL as a valid modifier for Medicare Part B claims. Providers should submit a separate blood product charge for application of the blood

deductible (BL modifier) from a blood product charge to which the blood deductible should not apply. Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, §231 provides further instructions on billing for blood products using the BL modifier.

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 Pub. 100-01, Medicare General Information, Eligibility and Entitlement Manual, chapter 3, §20.5-20.54 (formerly MCM 2455):
P9010, P011, 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 §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

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
4144.1	Carriers shall retrieve the 2006 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY06.V1103 from the CMS mainframe on or after November 3, 2005. 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	X	
4144.2	Intermediaries shall retrieve the 2006 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY06.V1118.FI from the CMS mainframe on or after November 18, 2005. 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., intermediary name and number).	X				X			X	
4144.3	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, 2004 through June 30, 2005, updated by the inflation-index update for year 2006 of 2.5 percent. When these services are performed for hospital based renal dialysis facility patients, intermediaries shall determine payment on a reasonable cost basis.	X		X		X	X	X	X	
4144.4	Contractors shall establish the fee for laboratory travel code P9603 at $0.935 per mile and for code P9604 at $9.35 per flat rate trip basis effective for dates of service on or after September 1, 2005. Contractors need not	X		X			X	X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	search their files to either retract payment or retroactively pay claims for laboratory travel fee codes P9603 and P9604, however, contractors should adjust claims if they are brought to their attention.									
4144.5	Effective January 1, 2006, contractors and shared system maintainers shall update their files to accept the HCPCS modifier BL *Special Acquisition of Blood and Blood Products* as a valid modifier for outpatient Medicare Part B claims from physician offices, independent laboratories, renal dialysis and other outpatient settings. Intermediaries have implemented the BL modifier for OPPS providers and shall update their files to accept the BL modifier submitted by other Part B providers. Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, §231 provides further instructions on billing for blood products using the BL modifier.	X		X		X	X	X	X	
4144.6	On or before March 31, 2006, carriers shall establish gap-fill amounts and submit this information to their ROs and the ROs should transmit this information to mary.stevenson@cms.hhs.gov and anita.greenberg@cms.hhs.gov. Carriers may revise gap-fill amounts and should report revisions no later than September 1, 2006. Carriers should also communicate the gap-fill amounts to corresponding intermediaries. Carriers should seek assistance from ROs to facilitate communication of the gap-fill amounts to intermediaries.			X						

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
4144.7	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn 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 and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	x		x			x	x		

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
4144.1	Attachments A B and C
4144.2	Instructions for calculating reasonable charge are located in Pub. 100-04, Medicare Claims Processing Manual chapter 23, §§80-80.8

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: January 1, 2006. September 1, 2005 for clinical laboratory travel fees (Codes P9603 and P9604). **Implementation Date:** January 3, 2006. September 1, 2005 for clinical laboratory travel fees (Codes P9603 and P9604). **Pre-Implementation Contact(s):** Anita Greenberg, anita.greenberg@cms.hhs.gov **Post-Implementation Contact(s):** Anita Greenberg, anita.greenberg@cms.hhs.gov	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

4 Attachments

ATTACHMENT A

CARRIER RECORD LAYOUT FOR DATA FILE

2006 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME: MU00.@BF12394.CLAB.CY06.V1103

Data Element Name	Picture	Location	Comment
HCPCS CODE	X(05)	1-5	
CARRIER NUMBER	X(05)	6-10	
LOCALITY	X(02)	11-12	00--Single State Carrier 01--North Dakota 02--South Dakota 20--Puerto Rico
60% LOCAL FEE	9(05)V99	13-19	
62% LOCAL FEE	9(05)V99	20-26	
60% NATL LIMIT AMT	9(05)V99	27-33	
62% NATL LIMIT AMT	9(05)V99	34-40	
60% PRICING AMT	9(05)V99	41-47	
62% PRICING AMT	9(05)V99	48-54	
GAP-FILL INDICATOR	X(01)	55-55	0--No Gap-fill Required 1--Carrier Gap-fill 2--Special Instructions Apply
MODIFIER	X(02)	56-57	
STATE LOCALITY	X(02)	58-59	
FILLER	X(01)	60-60	

ATTACHMENT B

INTERMEDIARY RECORD LAYOUT FOR DATA FILE

2006 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME:MU00.@BF12394.CLAB.CY06.V1118.FI

Data Element Name	Picture	Location	Comment
HCPCS	X(05)	1-5	
FILLLER	X(04)	6-9	
60% PRICING AMT	9(05)V99	10-16	
62% PRICING AMT	9(05)V99	17-23	
FILLER	X(07)	24-30	
CARRIER NUMBER	X(05)	31-35	
CARRIER LOCALITY	X(02)	36-37	00--Single State Carrier 01--North Dakota 02--South Dakota 20--Puerto Rico
STATE LOCALITY	X(02)	38-39	
FILLER	X(07)	40-60	

ATTACHMENT C

2006 CLINICAL LABORATORY FEE SCHEDULE

I. New Codes

80195
82271
82271QW
82272
82272QW
83037
83037QW
83631
83695
83700
83701
83704
83721QW
83880QW
83900
83907
83908
83909
83914
85576QW
86200
86355
86357
86367
86480
86586
86703QW
87209
87807QW
87900
86923
86960

II. Deleted Codes

82273
83715
83716
86064
86379
86587

III. Codes That Require Gap-Fill Amounts

83037 *Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use*

83037QW same as code 83037 above with the addition of the 'QW' modifier for a laboratory registered with only a certificate of waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

ATTACHMENT D

2006 CLINICAL LABORATORY FEE SCHEDULE

SUBMITTING 2006 GAP-FILL AMOUNTS

On or before March 31, 2006, carriers shall establish gap-fill amounts and submit this information to their ROs and the ROs shall transmit this information to mary.stevenson@cms.hhs.gov and anita.greenberg@cms.hhs.gov. Carriers may revise gap-fill amounts and should report revisions no later than September 1, 2006. Carriers should also communicate the gap-fill amounts to corresponding intermediaries. Carriers should seek assistance from ROs to facilitate communication of the gap-fill amounts to intermediaries.

Submit the gap-fill amounts in a right-justified format. Carriers should transmit these gap-fill data in an ASCII file with the following file specifications.

DATA SET NAME: CLXXXXX.TXT* (ASCII File)
(*Denotes carrier 5-digit number)

Data Element Name	Picture	Location	Comment
YEAR	X(4)	1-4	Set to 2006
HCPCS CODE	X(5)	5-9	
MODIFIER	X(2)	10-11	
CARRIER NUMBER	X(5)	12-16	
LOCALITY	X(2)	17-18	00--Single State Carrier 01--North Dakota 02--South Dakota 20--Puerto Rico
GAP-FILL AMOUNT	9(5)V99	19-25	Prior to any determination of a least costly alternative
LEAST COSTLY ALTERNATIVE AMOUNT	9(5)V99	26-32	
LEAST COSTLY ALTERNATIVE CODE	X(5)	33-37	