CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 363 **Date: November 5, 2004**

CHANGE REQUEST 3526

SUBJECT: 2005 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 update to the Medicare Part B clinical laboratory fees and codes.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: January 1, 2005
IMPLEMENTATION DATE: January 3, 2005

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
	Manual Instruction
	Confidential Requirements
	One-Time Notification
X	**Recurring Update Notification**

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 363	Date: November 5, 2004	Change Request 3526

SUBJECT: 2005 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 2005 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests and update 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 2005 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 2005 national minimum payment amount is $14.76 ($14.76 plus 0 percent update for 2005). 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 2005 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 4, 2004. Intermediaries should retrieve the data file on or after November 18, 2004.

Internet access to the 2005 clinical laboratory fee schedule data file should be available after November 18, 2004, at http://www.cms.hhs.gov/paymentsystems. 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 2005 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 2005 clinical laboratory fee schedule data file for carriers. Attachment B depicts the record layout of the 2005 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 2005 clinical laboratory fee schedule. The data file will include the new codes listed in Attachment C. In compliance with the Health Insurance Portability and Accountability Act (HIPAA), 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 26, 2004, CMS hosted a public meeting to solicit input on the payment relationship between 2004 codes and new 2005 Current Procedural Terminology (CPT) codes. The meeting announcement was published in the **Federal Register** on May 28, 2004, pages 30658-30659 and on the CMS Web site. 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 its Web site at http://www.cms.hhs.gov/paymentsystems. Additional written comments from the public were accepted until September 24, 2004.

Comments after the release of the 2005 laboratory fee schedule can be submitted to the following address so that CMS may consider them for the development of the 2006 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, 2006 implementation date, comments must be submitted before August 1, 2005.

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

The 2005 laboratory fee schedule includes separately payable fees for certain specimen collection methods (codes G0001, P9612, and P9615). The fees have been established in accordance with §1833(h)(4)(B) of the Act.

For dates of service January 1, 2005 through December 31, 2005, the personnel payment is $0.45 per mile. For dates of service January 1, 2005 through December 31, 2005, the standard mileage rate for transportation costs is $0.385. The 2005 payment for code P9603 is $.835 and for code P9604 is $8.35.

The 2005 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 of 1988 (CLIA).

For 2005, the clinical laboratory fee schedule will not include code G0001 and will include code 36415 *Collection of venous blood by venipuncture*. Code 36415 was released as not payable by Medicare in the 2005 HCPCS update file. However, code 36415 has now been activated to be payable by Medicare effective January 1, 2005. Thus, the HCPCS coverage indicator should be corrected to "C". The status indicator for OPPS should be "A". CPT code 36416 relating to a capillary specimen collection remains not payable by Medicare as a separate service.

Organ or Disease Oriented Panel Codes

Similar to prior years, the 2005 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.

Mapping Information for New and Revised Codes

New code 82045 is priced at the same rate as code 83880.

New code 82656 is priced at the same rate as code 83516.

New code 83009 is priced at the same rate as code 83013.

New code 83630 is priced at the same rate as code 83516.

New code 84163 is priced at the same rate as code 84702.

New code 84166 is priced at the sum of the rates of codes 84165 and 87015.

New code 84450QW is priced at the same rate as code 84450.

New code 86064 is priced at the same rate as code 86359.

New code 86335 is priced at the sum of the rates of codes 86334 and 87015.

New code 86379 is priced at the same rate as code 86359.

New code 86587 is priced at the same rate as code 86359.

New code 87807 is priced at the same rate as code 87804.

Gap-fill Payments for New Laboratory Tests

In accordance with §531(b) of the Benefits Improvement and Protection Act of 2000 (BIPA), 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, Chapter 13, §5.4). Joint Signature Memorandum RO-

2256, issued August 29, 2003 states that 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 2005, there are no new test codes to be gap-filled.

Laboratory Costs Subject to Reasonable Charge Payment in 2005

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 2005 is 3.3 percent.

Manual instructions for determining the reasonable charge payment can be found in the Medicare Claims Processing Manual, Pub. 100-04, 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, Medicare Claims Processing Manual, Pub. 100-04, 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).

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, Pub. 100-01, chapter 3, §20.5-20.54 (formerly 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 §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 86927 86930 86931 86932 86945 86950 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

C. Provider Education:

A Medlearn Matters 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 one week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. 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.

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	
3526.1	Contractors shall retrieve the 2005 clinical laboratory fee schedule data file from the CMS mainframe which will be available for carriers on November 4, 2004 and for intermediaries on November 18, 2004.	**X**		**X**		**X**	**X**	**X**	**X**	
3526.2	Contractors 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, 2003 through June 30, 2004, updated by the inflation-index update for year 2005 of 3.3 percent. When these services are performed for hospital based renal dialysis facility patients, payment is made on a reasonable cost basis.			**X**			**X**	**X**	**X**	
3526.3	For 2005, the clinical laboratory fee schedule will not include code G0001 and will include code 36415 *Collection of venous blood by venipuncture*. Code 36415 was released as not payable by Medicare in the 2005 HCPCS update file. However, code 36415 has now been activated to be payable by Medicare effective January 1, 2005. Thus, the HCPCS	**X**		**X**		**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	
	coverage indicator should be corrected to "C". The status indicator for OPPS should be "A".									

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
3526.1	Attachments A B and C
3526.2	Instructions for calculating reasonable charge are located Medicare Claims Processing Manual (Pub. 100-04) chapter 23, sections 80-80.8

B. Design Considerations:

X-Ref Requirement #	Recommendation for Medicare System Requirements
N/A	

C. Interfaces: N/A

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

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: January 1, 2005 **Implementation Date:** January 3, 2005	**Medicare Contractors shall implement these instructions within their current operating budgets.**

Pre-Implementation Contact(s): Anita Greenberg 410-786-4601 agreenberg@cms.hhs.gov **Post-Implementation Contact(s):** Anita Greenberg 410-786-4601 ageenberg@cms.hhs.gov	

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

ATTACHMENT A

CARRIER RECORD LAYOUT FOR DATA FILE

2005 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME: MU00.@BF12394.CLAB.CY05.V1104

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

2005 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME:MU00.@BF12394.CLAB.CY05.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

2005 CLINICAL LABORATORY FEE SCHEDULE

I. New Codes

80100QW
82045
82656
83009
83630
84163
84166
84450QW
86064
86335
86379
86587
87807

II. Deleted Codes

For 2005 there are no deleted codes.

III. Codes That Require Gap-Fill Amounts

For 2005 there are no new test codes to be gap-filled.