CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1400	**Date: DECEMBER 20, 2007**
	Change Request 5813

Subject: 2008 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

I. SUMMARY OF CHANGES: This recurring update notification provides specific instructions regarding the 2008 annual update for the clinical laboratory fee schedule and laboratory services subject to reasonable charge payment.

New / Revised Material
Effective Date: January 1, 2008
Implementation Date: January 7, 2008

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
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: 1400	Date: December 20, 2007	Change Request: 5813

SUBJECT: 2008 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

Effective Date: January 1, 2008

Implementation Date: January 7, 2008

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification provides instructions for the calendar year 2008 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 2008 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 2008 national minimum payment amount is $14.76 ($14.76 plus 0 percent update for 2008). 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 2008 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 8, 2007. Intermediaries should retrieve the data file on or after November 16, 2007. Internet access to the 2008 clinical laboratory fee schedule data file should be available after November 16, 2007, at www.cms.hhs.gov/ClinicalLabFeeSched. 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 2008 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 2008 clinical laboratory fee schedule data file for carriers. Attachment B depicts the record layout of the 2008 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 2008 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.

Public Comments

On July 16, 2007, CMS hosted a public meeting to solicit input on the payment relationship between 2007 codes and new 2008 Current Procedural Terminology codes. Notice of the meeting was published in the **Federal Register** on May 25, 2007 and on the CMS Web site on June 18, 2007. 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/ClinicalLabFeeSched. Additional written comments from the public were accepted until October 5, 2007. We will post a summary of the public comments and the rationale for our final payment determinations on our Web site.

Comments after the release of the 2008 laboratory fee schedule can be submitted to the following address so that CMS may consider them for the development of the 2009 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, 2009 implementation date, comments must be submitted before August 1, 2008.

Centers for Medicare & Medicaid Services (CMS)
Center for Medicare Management
Division of Ambulatory Services
Mailstop: C4-02-14
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Pricing Information

The 2008 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 January 1, 2008 through December 2008, the fee for clinical laboratory travel code P9603 is $0.935 per mile (round to $0.94 if necessary) 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. If there is a revision to the standard mileage rate for calendar year 2008, CMS will issue a separate instruction on the clinical laboratory travel fees.

The 2008 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 2008 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.

The CPT Editorial Panel created code 80047 *Basic metabolic panel (Calcium, ionized)* which is an automated multi-channel chemistry (AMCC) code. New code 80047 is comprised of eight component test codes (see below). Also, new code 80047 is not a replacement for code 80048 *Basic metabolic panel*. Both codes 80048 and 80047 are included in the 2008 clinical laboratory fee schedule. Business requirement 5813.5 provides instructions for payment of new code 80047 effective January 1, 2008. Additional business requirements to update the automated multi-channel chemistry code (AMCC) Panel Payment Algorithm will be issued in a separate instruction with timeframes for implementation.

80047 Basic metabolic panel (Calcium, ionized)

- Calcium; ionized (82330)
- Carbon dioxide (82374)
- Chloride (82435)
- Creatinine (82565)
- Glucose (82947)
- Potassium (84132)
- Sodium (84295)
- Urea Nitrogen (BUN) (84520)

In accordance with the Internet Only Manual 100-04, 40.6.1, the new panel code 80047 cannot be billed for services ordered through an ESRD facility. All tests billed for services ordered through an ESRD facility must be billed individually, not in an organ disease panel.

Mapping Information

New code 80047 is priced at the same rate as code 80048.
Note: Final payment is determined by the automated multi-channel chemistry (AMCC) Panel Payment Algorithm.

New code 82310QW is priced at the same rate as code 82310.

New code 82565QW is priced at the same rate as code 82565.

New code 82610 is priced at the same rate as code 83883.

New code 83655QW is priced at the same rate as code 83655.

New code 83993 is priced at the same rate as code 83631.

New code 84704 is priced at the same rate as code 84702.

New code 86356 is priced at the same rate as code 86361.

New code 87500 is priced at the same rate as code 87641.

New code 87809 is priced at the same rate as code 87802.

New code 89321QW is priced at the same rate as code 89321.

New code 89322 is priced at the sum of the rates of codes 89320 and 85007.

New code 89331 is priced at the sum of the rates of codes 89320 and 87015.

New automated multi-channel chemistry code ATP23 is priced at the same rate as code ATP22.

Laboratory Costs Subject to Reasonable Charge Payment in 2008

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 2008 is 2.7 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 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 P9043 P9044 P9048 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, 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 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	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5813.1	Carriers shall retrieve the 2008 Clinical Laboratory Fee Schedule data file (filename: MU00@BF12394.CLAB.CY08.V1203 from the CMS mainframe on or after November 8, 2007. Carriers shall notify of successful receipt via email 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			
5813.2	Intermediaries shall retrieve the 2008 Clinical Laboratory Fee Schedule data file (filename: MU00@BF12394.CLAB.CY08.V1203.FI. FI from the CMS mainframe on or after November 16, 2007. Carriers shall notify of successful receipt via email 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				
5813.3	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, 2006 through June 30, 2007, updated by the inflation-index update for year 2008 of 2.7 percent. Intermediaries shall determine payment on a reasonable cost basis when these services are performed for	X		X	X			X	X			

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	hospital based renal dialysis facility patients.											
5813.4	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 January 1, 2008. If there is a revision to the standard mileage rate for calendar year 2008, CMS will issue a separate instruction on the clinical laboratory travel fees.	X		X	X				X			
5813.5	Contractors shall include new chemistry panel code 80047 *Basic metabolic panel (Calcium, ionized)* as an automated multi-channel chemistry code (AMCC): 80047 Basic metabolic panel (Calcium ionized) ionized) • Calcium; ionized (82330) • Carbon dioxide (82374) • Chloride (82435) • Creatinine (82565) • Glucose (82947) • Potassium (84132) • Sodium (84295) • Urea Nitrogen (BUN) (84520) **Note**: New code 80047 is not a replacement for code 80048 *Basic metabolic panel*. Both codes 80048 and 80047 are included in the 2008 clinical laboratory fee schedule. Effective January 1, 2008, payment for code 80047 is made at the automated test panel (ATP07) amount. Code 82330 *Calcium; ionized* is paid at the existing fee schedule rate. Additional business requirements to update the automated multi-channel chemistry code (AMCC) Panel Payment Algorithm for new code	X		X	X			X	X			

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	80047 will be issued in a separate instruction with timeframes for implementation.											

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5813.6	A provider education article related to this instruction will be available at 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 and incorporated into any educational events on this topic. 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

A. For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
5813.1	Attachments A, B, and C

V. CONTACTS

Pre-Implementation Contact(s):
Anita Greenberg at anita.greenberg@cms.hhs.gov

VI. FUNDING

A. ***For TITLE XVIII Contractors*:**

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

B. ***For Medicare Administrative Contractors (MAC)*:**

The contractor is hereby advised that this constitutes technical direction as defined in your contract. We do not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified 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.

3 Attachments

ATTACHMENT A

CARRIER RECORD LAYOUT FOR DATA FILE

2008 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME: MU00.@BF12394.CLAB.CY08.V1108

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

2008 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME:MU00.@BF12394.CLAB.CY08.V1116.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

2008 CLINICAL LABORATORY FEE SCHEDULE

I. New Codes

80047
82310QW
82565QW
82610
83655QW
83993
84704
86356
87500
87809
89321QW
89322
89331
ATP23

II. Deleted Codes

86586
G0265
G0266

III. Codes That Require Gap-Fill Amounts

For 2008, there are no new test codes to be gap-filled.