CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2365	**Date: December 9, 2011**
	Change Request 7654

SUBJECT: Calendar Year (CY) 2012 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 2012 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. The attached Recurring Update Notification applies to Chapter 16, Section 20.2.

EFFECTIVE DATE:* January 1, 2012
IMPLEMENTATION DATE: January 3, 2012

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:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:
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:

Recurring Update Notification

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 2365	Date: December 9, 2011	Change Request: 7654

SUBJECT: Calendar Year (CY) 2012 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: January 1, 2012

IMPLEMENTATION DATE: January 3, 2012

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the CY 2012 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: See below.

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 2012 is 0.65 percent. The annual update to local clinical laboratory fees for CY 2012 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 2012 is 3.6 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 2012 national minimum payment amount is $14.97 ($14.87 plus (0.65) percent update for CY 2012). 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.

Molecular Pathology Procedure Test Codes

Beginning January 1, 2012, there will be 101 additional Molecular Pathology Procedure test codes established by the American Medical Association (AMA). For payment purposes under the Clinical Laboratory Fee Schedule (CLFS), these test codes will be assigned a "B" indicator – "Payment for covered services are always bundled into payment for other services not specified. There will be no RVUs or payment amounts for these codes and no separate payment is ever made. When these services are covered, payment for them is subsumed by the payment for the services to which they are incident (an example is a telephone call from a hospital nurse regarding care of a patient)."

However, each of these new Molecular Pathology Procedure test codes represents a test that is currently being utilized and which may be billed to Medicare. When these types of tests are billed to Medicare, we understand that existing Common Procedural Terminology (CPT) test codes are "stacked" to represent a given test. For example, Laboratory A has a genetic test that is generally billed to Medicare in the following manner – 83891 (one time) + 83898 (multiple times) + 83904 (multiple times) + 83909 (multiple times) + 83912 (one time) – in order to represent the performance of the entire test. If the new CPT test coding structure were active, Laboratory A would bill Medicare the new, single CPT test code that corresponds to the test represented by the "stacked" codes in the example above rather than billing each component of the test separately.

As of January 1, 2012, Medicare requests that Medicare claims for Molecular Pathology Procedures reflect both the existing CPT "stacked" test codes that are required for payment and the new single CPT test code that would be used for payment purposes if the new CPT test codes were active. Referring to the example above, Laboratory A would report the existing stacked set of codes that are required to receive payment [i.e., 83891 (one time) + 83898 (multiple times) + 83904 (multiple times) + 83909 (multiple times) + 83912 (one time)] along with the new, single CPT test code that corresponds to the test represented by the "stacked" test codes. While the allowed charge amount will be $0.00 for the new Molecular Pathology Procedure test codes that carry the "B" indicator, Medicare requests that Medicare claims also reflect a charge for the non-payable service.

Following are the CY 2012 Molecular Pathology Procedure test codes:

1. 81200
2. 81205
3. 81206
4. 81207
5. 81208
6. 81209
7. 81210
8. 81211
9. 81212
10. 81213
11. 81214
12. 81215
13. 81216
14. 81217
15. 81220
16. 81221
17. 81222
18. 81223
19. 81224
20. 81225
21. 81226
22. 81227
23. 81228
24. 81229

25. 81240
26. 81241
27. 81242
28. 81243
29. 81244
30. 81245
31. 81250
32. 81251
33. 81255
34. 81256
35. 81257
36. 81260
37. 81261
38. 81262
39. 81263
40. 81264
41. 81265
42. 81266
43. 81267
44. 81268
45. 81270
46. 81275
47. 81280
48. 81281
49. 81282
50. 81290
51. 81291
52. 81292
53. 81293
54. 81294
55. 81295
56. 81296
57. 81297
58. 81298
59. 81299
60. 81300
61. 81301
62. 81302
63. 81303
64. 81304
65. 81310
66. 81315
67. 81316
68. 81317
69. 81318
70. 81319
71. 81330
72. 81331
73. 81332
74. 81340
75. 81341
76. 81342

77. 81350
78. 81355
79. 81370
80. 81371
81. 81372
82. 81373
83. 81374
84. 81375
85. 81376
86. 81377
87. 81378
88. 81379
89. 81380
90. 81381
91. 81382
92. 81383
93. 81400
94. 81401
95. 81402
96. 81403
97. 81404
98. 81405
99. 81406
100. 81407
101. 81408

Access to Data File

The CY 2012 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 14, 2011. Intermediaries shall retrieve the data file on or after November 21, 2011. Internet access to the CY 2012 clinical laboratory fee schedule data file shall be available after November 21, 2011, 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 2012 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 18, 2011, CMS hosted a public meeting to solicit input on the payment relationship between CY 2011 codes and new CY 2012 CPT codes. Notice of the meeting was published in the Federal Register on February 25, 2011, and on the CMS web site approximately June 15, 2011. 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 28, 2011. 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 2012 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 2012, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2012 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 2012 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 86386 is priced at the same rate as code 82487.

New code 87389 is priced at the same rate as code 86703 plus 50% of code 87390.

Reconsidered code G0434 is priced at the same rate as code G0430.

Reconsidered code G0435 is priced at the same rate as code 87804.

Reconsidered code 83861 is priced at the same rate as code 84081.

Reconsidered code 87906 is priced at the same rate as 50% of code 87901.

Reconsidered code 86481 is priced at the same rate as code 86480 plus code 83520.

For CY 2012, there are no new test codes that need to be gap filled.

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 2012 is 3.6 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 Healthcare Common Procedure Coding System (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
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
89343
89344
89346
89352
89353
89354
89356

II. BUSINESS REQUIREMENTS 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	
7654.1	Carriers shall retrieve the CY 2012 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY12.V1114) from the CMS mainframe on or after November 14, 2011.	X			X						
7654.1.1	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						

Number	Requirement	Responsibility (place an "X" in each applicable column): A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers: FISS	MCS	VMS	CWF	OTHER
7654.2	Intermediaries shall retrieve the CY 2012 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY12.V1121.FI) from the CMS mainframe on or after November 21, 2011.	X		X							
7654.2.1	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							
7654.3	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						
7654.4	Carriers shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.	X			X						
7654.5	Carriers shall determine customary and prevailing charges by using data from July 1, 2010 through June 30, 2011, updated by the inflation-index update for year CY 2012 of 3.6 percent.	X			X						
7654.6	Intermediaries shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients.	X		X							
7654.7	If there is a revision to the standard mileage rate for CY 2012, CMS shall issue a separate instruction on the clinical laboratory travel fees.										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	
7654.8	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: N/A

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk at glenn.mcguirk@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *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.