CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3152	Date: December 19, 2014
	Change Request 9028

SUBJECT: Calendar Year (CY) 2015 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 2015 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. This Recurring Update Notification applies to chapter 16, section 20.

EFFECTIVE DATE: January 1, 2015

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

IMPLEMENTATION DATE: January 5, 2015

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 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 obliged 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

Attachment - Recurring Update Notification

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EFFECTIVE DATE: January 1, 2015

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IMPLEMENTATION DATE: January 5, 2015

I. GENERAL INFORMATION

- **A. Background:** This Recurring Update Notification (RUN) provides instructions for the CY 2015 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 applies to Chapter 16, section 20.
- **B.** Policy: 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 2015 is (-0.25) percent. The annual update to local clinical laboratory fees for CY 2015 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 2015 is 2.10 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 2015 national minimum payment amount is \$14.38 (\$14.42 plus (-0.25) percent update for CY 2015). 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.

Access to Data File

The CY 2015 clinical laboratory fee schedule data file shall be retrieved electronically through CMS' mainframe telecommunications system. Medicare Administrative Contractors (MACs) shall retrieve the data file on or after November 19, 2014. Internet access to the CY 2015 clinical laboratory fee schedule data file shall be available after November 17, 2014, at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/ClinicalLabFeeSched/clinlab.html. 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 2015 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. MACs should use the field "62% Pricing Amt" for payment to qualified laboratories of sole community hospitals.

Public Comments and Final Payment Determinations

On July 14, 2014, CMS hosted a public meeting to solicit input on the payment relationship between CY 2014 codes and new CY 2015 CPT codes. Notice of the meeting was published in the <u>Federal Register</u> on March 25, 2014, and on the CMS web site approximately April 1, 2014. 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.gov/Medicare/Medicare-Fee-for-Service-

Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html. Additional written comments from the public were accepted until October 30, 2014. CMS has posted a summary of the public comments and the rationale for the final payment determinations on the CMS web site at

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/ClinicalLabFeeSched/Downloads/CY2015-CLFS-Codes-Final-Determinations.pdf.

Pricing Information

The CY 2015 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 2015, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2015 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 2015 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

Existing code 83516QW is priced at the same rate as code 83516.

New code 80163 is priced at the same rate as code 80162.

New code 80165 is priced at the same rate as code 80164.

New code 81161 is to be gap filled.

New code 81246 is to be gap filled.

New code 81287 is to be gap filled.

New code 81288 is to be gap filled.

New code 81313 is to be gap filled.

New code 81410 is to be gap filled.

New code 81411 is to be gap filled.

New code 81415 is to be gap filled.

New code 81416 is to be gap filled.

New code 81417 is to be gap filled.

New code 81420 is to be gap filled.

New code 81425 is to be gap filled.

New code 81426 is to be gap filled.

New code 81427 is to be gap filled.

New code 81430 is to be gap filled.

New code 81431 is to be gap filled.

New code 81435 is to be gap filled.

New code 81436 is to be gap filled.

New code 81440 is to be gap filled.

New code 81445 is to be gap filled.

New code 81450 is to be gap filled.

New code 81455 is to be gap filled.

New code 81460 is to be gap filled.

New code 81465 is to be gap filled.

New code 81470 is to be gap filled.

New code 81471 is to be gap filled.

New code 83006 is priced at the same rate as code 82777.

New code 87505 is priced at the same rate as code 87631.

New code 87506 is priced at the same rate as code 87632.

New code 87507 is priced at the same rate as code 87633.

New code 87623 is priced at the same rate as code 87621.

New code 87624 is priced at the same rate as code 87621.

New code 87625 is priced at the same rate as code 87621.

New code 87806 is priced at the same rate as code 87389.

New code G6030 is priced at the same rate as code 80152.

New code G6031 is priced at the same rate as code 80154.

New code G6032 is priced at the same rate as code 80160.

New code G6034 is priced at the same rate as code 80166.

New code G6035 is priced at the same rate as code 80172.

New code G6036 is priced at the same rate as code 80174.

New code G6037 is priced at the same rate as code 80182.

New code G6038 is priced at the same rate as code 80196.

New code G6039 is priced at the same rate as code 82003.

New code G6040 is priced at the same rate as code 82055.

New code G6041 is priced at the same rate as code 82101.

New code G6042 is priced at the same rate as code 82145.

New code G6043 is priced at the same rate as code 82205.

New code G6044 is priced at the same rate as code 82520.

New code G6045 is priced at the same rate as code 82646.

New code G6046 is priced at the same rate as code 82649.

New code G6047 is priced at the same rate as code 82651.

New code G6048 is priced at the same rate as code 82654.

New code G6049 is priced at the same rate as code 82666.

New code G6050 is priced at the same rate as code 82690.

New code G6051 is priced at the same rate as code 82742.

New code G6052 is priced at the same rate as code 83805.

New code G6053 is priced at the same rate as code 83840.

New code G6054 is priced at the same rate as code 83858.

New code G6055 is priced at the same rate as code 83887.

New code G6056 is priced at the same rate as code 83925.

New code G6057 is priced at the same rate as code 84022.

New code G6058 is priced at the same rate as code 80102.

New code G0464 is priced at the same rate as sum of codes 81315, 81275, and 82274.

Existing code 80440 is to be deleted.

Existing code 82000 is to be deleted.

Existing code 82055 is to be deleted.

Existing code 82055QW is to be deleted.

Existing code 82953 is to be deleted.

Existing code 82975 is to be deleted.

Existing code 82980 is to be deleted.

Existing code 83008 is to be deleted.

Existing code 83055 is to be deleted.

Existing code 83071 is to be deleted.

Existing code 83634 is to be deleted.

Existing code 83866 is to be deleted.

Existing code 84127 is to be deleted.

Existing code 87001 is to be deleted.

Existing code 87620 is to be deleted.

Existing code 87621 is to be deleted.

Existing code 87622 is to be deleted.

Existing code 80102 is to be deleted.

Existing code 80152 is to be deleted.

Existing code 80154 is to be deleted.

Existing code 80160 is to be deleted.

Existing code 80166 is to be deleted.

Existing code 80172 is to be deleted.

Existing code 80174 is to be deleted.

Existing code 80182 is to be deleted.

Existing code 80196 is to be deleted.

Existing code 82003 is to be deleted.

Existing code 82101 is to be deleted.

Existing code 82145 is to be deleted.

Existing code 82205 is to be deleted.

Existing code 82520 is to be deleted.

Existing code 82646 is to be deleted.

Existing code 82649 is to be deleted.

Existing code 82651 is to be deleted.

Existing code 82654 is to be deleted.

Existing code 82666 is to be deleted.

Existing code 82690 is to be deleted.

Existing code 82742 is to be deleted.

Existing code 83805 is to be deleted.

Existing code 83840 is to be deleted.

Existing code 83858 is to be deleted.

Existing code 83887 is to be deleted.

Existing code 83925 is to be deleted.

Existing code 84022 is to be deleted.

Laboratory Costs Subject to Reasonable Charge Payment in CY 2015

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 2015 is 2.1 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 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, P9045, P9046, and P9047, should be obtained from the Medicare Part B drug pricing files.
Transfusion Medicine
86850
86860
86870
86880
86885
86886
86890
86891
86900
86901
86902
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
Reproductive Medicine Procedures 89250
89250
89250 89251
89250 89251 89253
89250 89251 89253 89254
89250 89251 89253 89254 89255
89250 89251 89253 89254 89255 89257
89250 89251 89253 89254 89255 89257 89258
89250 89251 89253 89254 89255 89257 89258 89259
89250 89251 89253 89254 89255 89257 89258 89259 89260
89250 89251 89253 89254 89255 89257 89258 89259 89260 89261

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility											
			A/B MA(D M E	System			Shared- System Maintainers				Other
		A	В	H H H	M A C	_	M C S	V M S	_				
9028.1	Contractors shall retrieve and implement the CY 2015 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY15.V1117) from the CMS mainframe on or after November 17, 2014.		X							VDCs			
9028.1.1	MACs 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., contractor name and number).		X										
9028.2	Contractors shall retrieve and implement the CY 2015 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY15.V1117.FI) from the CMS mainframe on or after November 17, 2014.	X								VDCs			

Number	Requirement	Responsibility										
			A/B MAC		*				Sys	red- tem aine		Other
		A	В	H H H	M A C	F I S	M C S	V M S	C W F			
9028.2.1	Contractors 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., contractor name and number).	X								VDCs		
9028.3	MACs 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									
9028.4	MACs shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.		X									
9028.5	MACs shall determine customary and prevailing charges by using data from July 1, 2013 through June 30, 2014, updated by the inflation-index update for year CY 2015 of 2.10 percent.		X									
9028.6	MACs shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients.	X										
9028.7	If there is a revision to the standard mileage rate for CY 2015, CMS shall issue a separate instruction on the clinical laboratory travel fees.									CMS		

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spoi	nsib	ility	
			A/B		D	С
		1	MAC	\mathbf{C}	M	Е
					Е	D
		A	В	Н		I
				Н	M	
				Н	Α	
					C	
9028.8	MLN Article: A provider education article related to this instruction will be	X	X			
	available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-					
	Network-MLN/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 sites and include information about it in a listsery message within one week					
	of the availability of the provider education article. In addition, the provider					
	education article shall be included in the contractor's next regularly scheduled					

Number	Requirement				bility		
			A/B		D	C	
		1	MAC	7)	M	Е	
					Е	D	
		Α	В	Н		Ι	
				Н	M		
				Н	A		
					C		
	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.						

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk, 410-786-5723 or Glenn.McGuirk@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0