CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3420	**Date: December 11, 2015**
	Change Request 9465

SUBJECT: Calendar Year (CY) 2016 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 2016 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, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 4, 2016

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 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

Attachment - Recurring Update Notification

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SUBJECT: Calendar Year (CY) 2016 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: January 1, 2016
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I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the CY 2016 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: Update to Fees

In accordance with Section 1833(h)(2)(A)(i) of the Social Security Act (the Act), the annual update to the local clinical laboratory fees for CY 2016 is 0.10 percent. The annual update to payments made on a reasonable charge basis for all other laboratory services for CY 2016 is 0.10 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 2016 national minimum payment amount is $14.39 ($14.38 times 0.10 percent update for CY 2016). 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 2016 clinical laboratory fee schedule data file shall be retrieved electronically through CMS' mainframe telecommunications system. A/B MAC Part B contractors shall retrieve the data file on or after November 16, 2015. A/B MAC Part A contractors shall retrieve the data file on or after November 16, 2015. Internet access to the CY 2016 clinical laboratory fee schedule data file shall be available after November 16, 2015, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.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 2016 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. A/B MAC Part A contractors should use the field "62% Pricing Amt" for payment to qualified laboratories of sole community hospitals.

Public Comments and Final Payment Determinations

On July 16, 2015, CMS hosted a public meeting to solicit input on the payment relationship between CY 2015 codes and new CY 2016 CPT codes. Notice of the meeting was published in the Federal Register on May 7, 2015, and on the CMS web site approximately May 11, 2015. 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 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html. Additional written comments from the public were accepted until October 26, 2015. CMS has posted a summary of the public comments and the rationale for the final payment determinations on the CMS web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2016-CLFS-Codes-Final-Determinations.pdf.

Pricing Information

The CY 2016 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 2016, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2016 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 2016 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 G0477 is priced at the same rate as 0.75 times code G0434.

New code G0478 is priced at the same rate as code G0434.

New code G0479 is priced at the same rate as 4.00 times code G0434.

New code G0480 is priced at the same rate as 3.25 times code 82542.

New code G0481 is priced at the same rate as 5.00 times code 82542.

New code G0482 is priced at the same rate as 6.75 times code 82542.

New code G0483 is priced at the same rate as 8.75 times code 82542.

New code 87651QW is priced at the same rate as code 87651.

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

New code 87502QW is priced at the same rate as code 87502.

New code 86780QW is priced at the same rate as code 86780.

New code 87650QW is priced at the same rate as code 87650.

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

New code 86850 is priced at the same rate as code 86902.

New code 80081 is priced at the same rate as the sum of codes 85025, 87340, 87389, 86762, 86592, 86850, 86900, and 86901.

New code 80055 is priced at the same rate as the sum of codes 85025, 87340, 86762, 86592, 86850, 86900, and 86901.

New code G0472 is priced at the same rate as code 86803.

New code G0472QW is priced at the same rate as code 86803.

New code 81162 is priced at the same rate as the sum of 0.90 times code 81211, and 0.90 times code 81213.

New code 81170 is priced at the same rate as code 81235.

New code 81218 is priced at the same rate as code 81235.

New code 81219 is priced at the same rate as code 81245.

New code 81272 is priced at the same rate as code 81235.

New code 81273 is priced at the same rate as code 81270.

New code 81276 is priced at the same rate as code 81275.

New code 81311 is priced at the same rate as 1.50 times code 81275.

New code 81314 is priced at the same rate as code 81235.

New code 81528 is priced at the same rate as the sum of codes 81315, 81275, and 82274.

New code 81535 is priced at the same rate as the sum of 2.00 times code 88239, and code 87900.

New code 81536 is priced at the same rate as code 87900.

New code 81412 is to be gap filled.

New code 81432 is to be gap filled.

New code 81433 is to be gap filled.

New code 81434 is to be gap filled.

New code 81437 is to be gap filled.

New code 81438 is to be gap filled.

New code 81442 is to be gap filled.

New code 81490 is to be gap filled.

New code 81493 is to be gap filled.

New code 81525 is to be gap filled.

New code 81538 is to be gap filled.

New code 81540 is to be gap filled.

New code 81545 is to be gap filled.

New code 81595 is to be gap filled.

New code 0009M is to be gap filled.

New code 0010M is to be gap filled.

Existing code G0431 is to be deleted.

Existing code G0434 is to be deleted.

Existing code G0434QW is to be deleted.

Existing code G0464 is to be deleted.

Existing code G6030 is to be deleted.

Existing code G6031 is to be deleted.

Existing code G6032 is to be deleted.

Existing code G6034 is to be deleted.

Existing code G6035 is to be deleted.

Existing code G6036 is to be deleted.

Existing code G6037 is to be deleted.

Existing code G6038 is to be deleted.

Existing code G6039 is to be deleted.

Existing code G6040 is to be deleted.

Existing code G6041 is to be deleted.

Existing code G6042 is to be deleted.

Existing code G6043 is to be deleted.

Existing code G6044 is to be deleted.

Existing code G6045 is to be deleted.

Existing code G6046 is to be deleted.

Existing code G6047 is to be deleted.

Existing code G6048 is to be deleted.

Existing code G6049 is to be deleted.

Existing code G6050 is to be deleted.

Existing code G6051 is to be deleted.

Existing code G6052 is to be deleted.

Existing code G6053 is to be deleted.

Existing code G6054 is to be deleted.

Existing code G6055 is to be deleted.

Existing code G6056 is to be deleted.

Existing code G6057 is to be deleted.

Existing code G6058 is to be deleted.

Existing code 82486 is to be deleted.

Existing code 82487 is to be deleted.

Existing code 82488 is to be deleted.

Existing code 82489 is to be deleted.

Existing code 82491 is to be deleted.

Existing code 82492 is to be deleted.

Existing code 82541 is to be deleted.

Existing code 82543 is to be deleted.

Existing code 82544 is to be deleted.

Existing code 83788 is to be deleted.

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 2016 is 0.1 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

89250

89251

89253

89254

89255

89257

89258

89259

89260

89261

89264

89268

89272

89280

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89356

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9465.1	A/B MAC Part B contractors shall retrieve and implement the CY 2016 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY16.V1116) from the CMS mainframe on or after November 16, 2015.		X							VDCs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9465.1.1	A/B MAC Part B 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., A/B MAC Part B name and number).		X							VDCs
9465.2	A/B MAC Part A contractors shall retrieve and implement the CY 2016 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY16.V1116.FI) from the CMS mainframe on or after November 16, 2015.	X								VDCs
9465.2.1	A/B MAC Part A 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., A/B MAC Part A name and number).	X								VDCs
9465.3	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							
9465.4	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.		X							
9465.5	A/B MAC Part B contractors shall determine customary and prevailing charges by using data from July 1, 2014 through June 30, 2015, updated by the inflation-index update for year CY 2016 of 0.10 percent.		X							
9465.6	A/B MAC Part A contractors shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients.	X								
9465.7	If there is a revision to the standard mileage rate for CY 2016, CMS shall issue a separate instruction on the clinical laboratory travel fees.									CMS

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9465.8	MLN Article: A provider education article related to this instruction will be 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 listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's 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			

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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