DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters® Number: MM9028 | **Related Change Request (CR) #: CR 9028**

Related CR Release Date: December 19, 2014 | **Effective Date: January 1, 2015**

Related CR Transmittal #: R3152CP | **Implementation Date: January 5, 2015**

Calendar Year (CY) 2015 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

Note: This article was revised December 6, 2016, to add a reference to MLN Matters Article SE1619 that provides guidance to assist the laboratory community in meeting requirements under Section 1834A of the Social Security Act (the "Act") for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). It includes clarifications for determining whether a laboratory meets the requirements to be an "applicable laboratory" in addition to other clarifications. All other information is unchanged.

Provider Types Affected

This MLN Matters® article is intended for clinical diagnostic laboratories who submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9028 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. Make sure your billing staffs are aware of these updates.

Background

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 Affordable

Care Act 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 Affordable Care Act.

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.

Key Points of CR9028

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

Internet access to the CY 2015 clinical laboratory fee schedule data file is available at **http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html** on the Centers for Medicare & Medicaid Services (CMS) website. Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, may use the Internet to retrieve the CY 2015 clinical laboratory fee schedule; available in multiple formats, including Excel, text, and comma delimited.

Public Comments

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 Federal Register 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/index.html?redirect=/ClinicalLabFeeSched.** 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 at **http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2015-CLFS-Codes-Final-Determinations.pdf** on the CMS web site.

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 are established in accordance with Section 1833(h)(4)(B) of the Act.

The fees for clinical laboratory travel codes P9603 and P9604 are updated annually. 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 to 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

As in 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 codes to be gap filled are 81161, 81246, 81287, 81288, 81313, 81410, 81411, 81415, 81416, 81417, 81420, 81425, 81426, 81427, 81430, 81431, 81435, 81436, 81440, 81445, 81450, 81455, 81460, 81465, 81470, and 81471.

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.

The following existing codes are to be deleted: 80440, 82000, 82055, 82055QW, 82953, 82975, 82980, 83008, 83055, 83071, 83634, 83866, 84127, 87001, 87620, 87621, 87622, 80102, 80152, 80154, 80160, 80166, 80172, 80174, 80182, 80196, 82003, 82101, 82145,

82205, 82520, 82646, 82649, 82651, 82654, 82666, 82690, 82742, 83805, 83840, 83858, 83887, 83925, and 84022.

Laboratory Costs Subject to Reasonable Charge Payment in CY 2011

For outpatients, the following codes are paid under a reasonable charge basis. 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, available at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c23.pdf** on the CMS website. 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, the "Medicare Claims Processing Manual," Chapter 8, Section 60.3, which is available at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf**, instructs that the reasonable charge basis applies. 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 Product Codes

Blood Product codes are 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, and P9060.

Also, payment for codes P9010, 9016, P9021, P9022, P9038, P9039, P9040, P9051, P9054, P9056, P9057, and P9058 should be applied to the blood deductible as instructed in the "Medicare General Information, Eligibility and Entitlement Manual," Chapter 3, Section 20.5 through 20.5.4 (available at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c03.pdf**).

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 Codes

Transfusion Medicine codes are 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, and 86985.

Reproductive Medicine Procedures

Reproductive Medicine Procedure codes are 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, and 89356.

MACs will not search their files to either retract payment or retroactively pay claims; however, they should adjust claims that you bring to their attention.

Additional Information

The official instruction, CR9028, issued to your MAC regarding this change is available at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3152CP.pdf** on the CMS website.

If you have questions please contact your MAC at their toll-free number. The number is available at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html** under - How Does It Work?

Document History

Date of Change	Description
December 6, 2016	This article was revised to add a reference to MLN Matters® Article SE1619 that provides guidance to assist the laboratory community in meeting the requirements under Section 1834A of the Social Security Act (the "Act") for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). It includes clarifications for determining whether a laboratory meets the requirements to be an "applicable laboratory" in addition to other clarifications.
December 22, 2014	Initial article released