The Impact of PAMA Regulations on POLs

Part 3

John T. Daly, M.D.
Chief Medical Officer, COLA

COLA

Guidance to Laboratories for PAMA Data Collection

- Additional guidance on data collection released by CMS the week of September 5, 2016
- Fee schedule data reporting template included

PAMA Regulations

The Clinical Laboratory Fee Schedule (CLFS) final rule entitled "Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System" (CMS-1621-F) went on display in the Federal Register on June 17, 2016. The final CLFS rule implements section 216 of the Protecting Access to Medicare Act of 2014.

Under the final rule, laboratories and physician offices are required to report private payor rate and volume data if they have more than $12,500 in Medicare revenues from laboratory services on the CLFS and they receive more than 50 percent of their Medicare revenues from laboratory and physician services during a data collection period. Laboratories will collect private payor data from January 1, 2016 through June 30, 2016 and report it to CMS by March 31, 2017. CMS will post the new Medicare CLFS rates (based on weighted median private payor rates) in November 2017 that will be effective on January 1, 2018.

Tests that meet the criteria for being considered new advanced tests will be paid at actual list charge during an initial period of three calendar quarters. Once the initial period is over, payment for new advanced tests would be based on the weighted median private payor rate reported by the single laboratory that performs the new ADLT. Advanced tests are tests that are furnished by only one laboratory that include a unique algorithm and, at a minimum, are an analysis of RNA, DNA or proteins or are cleared or approved by the U.S. Food and Drug Administration (FDA).

For More Information about CMS -1621-F:

- Final rule published June 23, 2016
- Press release
- Fact sheet

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percent of their Medicare revenues from laboratory and physician services during a data collection period. Laboratories will collect private payor data from January 1, 2016 through June 30, 2016 and report it to CMS by March 31, 2017. CMS will post the new Medicare CLFS rates (based on weighted median private payor rates) in November 2017 that will be effective on January 1, 2018.

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For More Information about CMS -1621-F:

- Final rule published June 23, 2016
- Press release
- Fact sheet
- Frequently Asked Questions
- July 6, 2016 call slides and transcript
- MLN SE1619 [PDF, 115KB] - Guidance to Laboratories for Data Collection and Reporting
- MLN SE1620 [PDF, 217KB] - Clinical Laboratory Fee Schedule Data Reporting Template

Questions regarding the CLFS final rule may be sent to the CLFS inquiries resource mail box via the following email address: CLFS_Inquiries@cms.hhs.gov.

Downloads

Frequently Asked Questions Regarding CMS 1621 F: Medicare Program - Medicare Clinical Diagnostic Laboratory Test Payment System Final Rule [PDF, 298KB]

CLFS Applicable Information HCPCS Codes [ZIP, 201KB]

CLFS Data Reporting Template [ZIP, 298B]

Related Links

CMS-1621-P

THANK YOU FOR YOUR ATTENTION

9881 Broken Land Parkway, Suite 200, Columbia, MD 21046-1195 Phone 1.800.981.9883 | Fax 410.381.8611 www.cola.org