DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
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**CMS NEWS**

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## Medicare Will Use Private Payor Prices to Set Payment Rates for Clinical Diagnostic Laboratory Tests Starting in 2018

Today, the Centers for Medicare & Medicaid Services (CMS) released a final rule implementing Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), requiring laboratories performing clinical diagnostic laboratory tests to report the amounts paid by private insurers for laboratory tests. Medicare will use these private insurer rates to calculate Medicare payment rates for laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS) beginning January 1, 2018. The final rule includes provisions to ease administrative burdens for physician office laboratories and smaller independent laboratories.

In response to public comments, CMS moved implementation of the new payment system from January 1, 2017 to January 1, 2018 to allow laboratories sufficient time to develop the information systems necessary to collect, review, and verify data before reporting applicable information to CMS. This will also allow time for CMS to perform independent validation and testing of the CMS system through which laboratories will report applicable information, and allow laboratories to perform end-to-end testing of their systems with CMS' system.

Medicare pays approximately $7 billion a year to Medicare-enrolled laboratories for more than 1,300 types of clinical laboratory tests on the CLFS. Medicare's current fee schedule rates have remained relatively unchanged since the current statutory methodology was established in 1984, apart from setting payments for new tests or implementing across-the-board statutory payment updates. Medicare-enrolled laboratories include entities ranging from national chains, which perform a large menu of tests to small regional operations, which may concentrate on specific populations such as nursing home residents. Physician offices may also perform certain laboratory tests that are paid for by Medicare.

The final rule will generally require reporting entities to report private payor rates and test volumes for laboratory tests if an applicable laboratory receives at least $12,500 in Medicare

revenues from laboratory services paid under the CLFS and more than 50 percent of its Medicare revenues from laboratory and/or physician services. This means that approximately 95 percent of all physician office laboratories and about half of independent laboratories will not fall under these requirements, easing administrative burdens for physician office labs and smaller independent labs while still capturing most of the CLFS spending on physician office and independent laboratories.

For the system's first year, laboratories will collect private payor data from January 1, 2016 through June 30, 2016, and report it to CMS between January 1, 2017 and March 31, 2017. CMS will calculate and post the new Medicare rates (equal to the weighted median of private payor rates for each test) by early November 2017. These rates will take effect on January 1, 2018.

Per statute, Medicare will pay a special category of tests, known as advanced diagnostic laboratory tests (ADLTs) at actual list charge for three calendar quarters. ADLTs are tests furnished by a single laboratory that also meet one of two additional criteria. . The first criteria requires that the test must be an analysis of RNA, DNA or proteins; include a unique algorithm; produce a result that predicts the probability a specific individual patient will develop a certain condition or respond to a particular therapy; and provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests. Alternatively, the second criteria requires that an ADLT is cleared or approved by the U.S. Food and Drug Administration.

Payment rates under the revised CLFS will be updated to reflect market rates paid by private payors every three years for most tests, except for ADLT rates, which will be updated every year, to reflect market rates paid by private payors.

The final rule is on display at the *Federal Register* and can now be downloaded from the *Federal Register* website at https://www.federalregister.gov/public-inspection. It will be published on June 23, 2016.

For a link to a Fact Sheet on the final rule, click here:
https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-17.html

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