DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services Room 352-G 200 Independence Avenue, SW Washington, DC 20201



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CMS Proposes New Medicare Clinical Diagnostic Laboratory Tests Fee Schedule
Proposed initiative would begin data collection process to set new payment rates

WASHINGTON (September 25, 2015) – The Centers for Medicare & Medicaid Services (CMS) today announced its next step in implementing the Protecting Access to Medicare Act of 2014 (PAMA), requiring clinical laboratories to report on private insurance payment amounts and volumes for lab tests. This data will be used to determine Medicare's payment for lab tests beginning January 1, 2017.

"Modernizing Medicare's payment for clinical lab tests is another example of our commitment to spending health care dollars more wisely," said CMS Deputy Administrator and Chief Medical Officer, Patrick Conway, M.D., M.S. "This demonstrates CMS' dedication to collaborating with private payors to improve the delivery system."

Medicare's current fee schedule for lab tests was first adopted in 1984 and has remained relatively unchanged except to establish payments for new tests or implement across-the-board statutory payment updates. Medicare pays approximately \$8 billion a year for clinical diagnostic laboratory tests. The new system will be updated every three years for clinical diagnostic laboratory tests (CDLTs) and every year for ADLTs to reflect market rates paid by private payers.

Medicare-enrolled laboratories are a mix of national chains that perform a large menu of tests and small regional operations that concentrate on a specific population, such as nursing home residents. Physician offices also perform certain tests that are paid by Medicare.

Under the proposed rule, certain laboratories would be required to report private payor rate and volume data if they receive at least \$50,000 in Medicare revenues from laboratory services and more than 50 percent of their Medicare revenues from laboratory and physician services.

Laboratories would collect private payor data from July 1, 2015 through December 31, 2015 and report it to CMS by March 31, 2016. CMS will post the new Medicare rates by November 1, 2016; these rates will be effective on January 1, 2017.

Tests that meet the criteria for being considered new ADLTs will be paid at actual list charge for a minimum of three quarters. ADLTs are tests that are furnished by only one laboratory and that either include a unique algorithm and are at a minimum an analysis of RNA or DNA, or are cleared or approved by the U.S. Food and Drug Administration (FDA).

CMS will solicit comments until November 25, 2015. Instructions on how to submit comments are found in the proposed rule.

The proposed rule will publish in the Federal Register on October 1, 2015 and can be downloaded from the *Federal Register* at https://www.federalregister.gov/public-inspection.

For a link to the fact sheet, click here.

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