Issue Brief

FEDERAL ISSUE BRIEF • June 20, 2016

KEY POINTS

- The new rule implements section 216 of the Protecting Access to Medicare Act of 2014 and uses private payer rates for laboratory tests from applicable laboratories to set the payment rates in the Clinical Laboratory Fee Schedule. The transition would decrease the amount of expenditures by 5.6 percent or $390 million in fiscal year 2018.
- CMS estimates that the five-year reduction will amount to 4.9 percent or $1.71 billion.

CMS Issues Final Rule Regarding Clinical Diagnostic Laboratory Test Payments

The Centers for Medicare and Medicaid Services has issued a final rule implementing section 216 of the Protecting Access to Medicare Act of 2014. PAMA significantly revises the Medicare clinical laboratory payment system. Private payer rates for laboratory tests from applicable laboratories will become the basis for revised Medicare payment rates for most laboratory tests on the Clinical Laboratory Fee Schedule beginning January 2018.

The rule is scheduled for publication in the June 23rd *Federal Register* A copy of the 245-page document is currently available at: https://www.federalregister.gov/articles/2016/06/23/2016-14531/medicare-program-medicare-clinical-diagnostic-laboratory-tests-payment-system. This link will be superseded when the regulation is published.

COMMENT

This not an easy rule to digest. While CMS has provided comprehensive information on its proposed rule, CMS does not provide easy to find final decision sections. Rather, changes are buried within the agency's responses to the comments received.

CMS says it expects the effect of changes to the Medicare program to be $390 million less in Part B program payments for CLFS tests furnished in FY 2018. The five-year impact is estimated to be $1.71 billion less and the 10-year impact is expected to result in $3.93 billion less in program payments.

Medicare pays approximately $7 billion a year under the current CLFS for Clinical Diagnostic Laboratory Tests. Using estimated amount of changes in CLFS spending, CMS estimates an overall percentage reduction in revenue of approximately -5.6 percent for FY 2018 (-$390 million/$7 billion = -5.6 percent); a 5-year percentage reduction of about 4.9 percent (-$1.71 billion /$35 billion = -4.9 percent) and a 10-year percentage reduction of approximately 5.6 percent (-$3.93 billion / $70 billion = -5.61 percent).

BACKGROUND

The CLFS provides payment for approximately 1,300 CDLTs. The CLFS was first adopted in 1984, and CLFS rates have only been updated since that time to establish payment for new tests or to make statutory across-the-board updates.

In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payer rates determined for the test, based on the data of applicable laboratories that is collected during a specified data collection period and reported to CMS during a specified data reporting period.

continued

4712 Country Club Drive
Jefferson City, MO 65109

P.O. Box 60
Jefferson City, MO 65102

573/893-3700
www.mhanet.com

MISSOURI HOSPITAL ASSOCIATION

DEFINITION OF APPLICABLE LABORATORY AND REPORTING REQUIREMENTS

PAMA defines applicable laboratories as having the majority of their Medicare revenues paid under the CLFS or the Physician Fee Schedule. CMS, using the National Provider Identifier, says an applicable laboratory is one that has more than 50 percent of its total Medicare revenues received under the CLFS and PFS.

PAMA allows CMS to develop a low volume or low expenditure threshold in designating which entities are applicable laboratories. In the final rule, CMS will generally exclude a laboratory from being an applicable laboratory, and thus from having to collect and report private payer data, if it is paid less than $12,500 under the CLFS during a data collection period. This exclusion will not apply to certain laboratories with respect to the Advanced Diagnostic Laboratory Tests they offer and furnish.

A hospital outreach laboratory that is independently enrolled in Medicare and has its own NPI would meet the definition of an applicable laboratory if at least 50 percent of its Medicare revenues are from CLFS and PFS services and its revenues from the CLFS are at least $12,500 during a data collection period.

CMS estimates that about 55 percent of independent laboratories and about 95 percent of physician office laboratories will be precluded from reporting private payer data as a result of the low expenditure criterion.

Laboratories must provide a Taxpayer Identification Number (TIN) and an NPI when they enroll in Medicare. To alleviate the potential administrative burden on the laboratory industry, CMS is applying the reporting requirements at the TIN level, so the TIN-level entity will report for all of its NPI-level components that are applicable laboratories.

The statute provides for civil monetary penalties of up to $10,000 per day, adjusted for inflation as required by the Inflation Adjustment Act Improvements Act of 2015, for each failure to report and/or each misrepresentation or omission in reporting private payer prices with respect to a CDLT.

DATA COLLECTION AND REPORTING

CMS is adopting a six-month data collection period. The first data collection period will be from January 1 through June 30, 2016. The first data reporting period (that is, the period during which data from the collection period will be submitted to CMS) will be from January 1, 2017 through March 31, 2017. All subsequent data collection and reporting periods for CDLTs, except for ADLTs, will follow this same data collection and reporting schedule, every three years. Reporting of private payer rates for ADLTs will occur on the same schedule except it will be on an annual basis.

ADVANCED DIAGNOSTIC LABORATORY TESTS

The statute defines an ADLT as a laboratory test that is covered under Medicare Part B and is offered and furnished only by a single laboratory, that is not sold for use by a laboratory other than the original developing laboratory (or a successor owner), and that meets one of the following criteria:

1. The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result;
2. the test is cleared or approved by the Food and Drug Administration (FDA);

continued

3. the test meets other similar criteria established by the Secretary.

CMS also will include tests that are solely an analysis of proteins as ADLTs.

CMS is adopting, as proposed, that an ADLT must include an empirically derived algorithm that yields a result that predicts the probability a specific patient will develop a certain condition or respond to a particular therapy, and must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

CMS also proposed and is adopting to require that laboratories present evidence and attest to the test's unique algorithm, that the test is not offered for sale by any other laboratory, and that the results of the test offer information that no other test can provide.

PRIVATE PAYER DEFINED

CMS incorporates PAMA's definition of the term "private payer" as:

- A health insurance issuer and a group health plan (as such terms are defined in section 2791 of the Public Health Service Act).
- A Medicare Advantage plan under Part C.
- Medicaid managed care organization (as defined in section 1903(m) [of the Social Security Act]).

SCHEDULE FOR IMPLEMENTATION

CMS is adopting the following schedule for implementation:

- First data collection period for determining calendar year 2018 CLFS payment rates: January 1, 2016 through June 30, 2016.
- First data reporting period for reporting entities to report private payer rate data to CMS for determining CY 2018 CLFS payment rates: January 1, 2017 through March 31, 2017.
- Annual laboratory public meeting for new tests: mid-July 2017. CMS will use crosswalking or gapfilling to set rates for new tests (that are not new ADLTs) for which there is no private payer data collected for CY 2018.
- CMS publishes preliminary CLFS rates for CY 2018: early September 2017. The public will have approximately 30 days, through early October 2017, to submit comments on the preliminary CY 2018 rates.
- CMS makes final CY 2018 CLFS rates available on the CMS website: early November 2017.
- Implementation date of new CLFS: January 1, 2018.

PAYMENT REDUCTIONS

PAMA states that the payment amount for a test cannot drop more than 10 percent as compared to the previous year's payment amount for the first three years after implementation of the new payment system, and not more than 15 percent per year for the subsequent three years. CMS finalized the payment reduction limit to correspond to the January 1, 2018, implementation of the private payer rate-based CLFS.

The following example shows how CMS will implement the payment reduction limit:

- If an existing test under the CLFS for CY 2017 has a payment rate of $20, but the weighted median private payer rate calculated during CY 2017 for CY 2018 (using January 1, 2016, through June 30, 2016 data) produces a payment rate of $15, then for CY 2018, the CLFS payment rate for the test becomes $18 ($20 minus $2), the maximum 10 percent reduction allowed from the prior year's price.

continued

- The following year, a 10 percent reduction would equal $1.80, lowering the total payment to $16.20 for CY 2019.
- The maximum reduction percentage allowed by the statute would continue to apply to the prior year's payment until the reduction becomes less than the applicable percentage (10 percent or 15 percent), after which the fee schedule payment will reflect the weighted median of the private payer rates for the test.

Section 1834A(b)(4)(A) of the Act states that the payment amounts established under this methodology for a year following a data collection period shall continue to apply until the year following the next data collection period. Moreover, section 1834A(b)(4)(B) of the Act specifies that the payment amounts established under section 1834A of the Act shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment).

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

MISSOURI HOSPITAL ASSOCIATION