DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
Room 352-G
200 Independence Avenue, SW
Washington, DC 20201

CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF COMMUNICATIONS

FACT SHEET

FOR IMMEDIATE RELEASE
June 17, 2016

Contact: CMS Media Relations
(202) 690-6145 | CMS Media Inquiries

Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule

Overview

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) added section 1834A to the Social Security Act (the Act), which requires revisions to the payment methodology for clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS). Under the final rule, reporting entities will be required to report private payor payment rates for laboratory tests and the corresponding volumes of tests. Private payor rates for laboratory tests from applicable laboratories will be the basis for the revised Medicare payment rates for most laboratory tests on the CLFS beginning in January 2018.

Background

Medicare pays for clinical diagnostic laboratory tests (CDLTs) under the CLFS. The CLFS provides payment for approximately 1,300 CDLTs, and Medicare pays approximately $7 billion per year for these tests.

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.

Payment for a new test code on the CLFS established after 1984 is based on either: crosswalking, where an existing test with similar methodology and resources is used as a basis for the payment amount; or gapfilling, where Medicare Administrative Contractors are tasked with developing a payment amount for a test for which there is no existing test with a similar methodology.

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 payor 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. A subset of tests on the CLFS -- advanced diagnostic laboratory tests (ADLTs) -- will have different data collection, reporting, and payment policies associated with them as required by the statute.

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 (PFS). Under the final rule, in response to comments, a laboratory (as defined by CMS's Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations), using its National Provider Identifier (NPI), is considered an applicable laboratory if more than 50 percent of its total Medicare revenues are received under the CLFS and PFS. This is a change in policy from the proposed rule where CMS proposed to use the Taxpayer Identification Numbers (TINs) as a mechanism for defining an applicable laboratory.

PAMA gives CMS the authority to develop a low volume or low expenditure threshold in designating which entities are applicable laboratories. Under the final rule, CMS will generally exclude a laboratory from being an applicable laboratory, and thus from having its private payor data reported, 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 (ADLTs) 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.

We estimate that about 55 percent of independent laboratories and about 95 percent of physician office laboratories will be precluded from reporting private payor data as a result of the low expenditure criterion. However, even though the low expenditure threshold will substantially reduce the number of physician offices and independent laboratories for which private payor rates must be reported, we estimate those physicians and laboratories for which private payor rates will be required to be reported account for approximately 92 percent of CLFS spending on physician office laboratories and approximately 99 percent of CLFS spending on independent laboratories.

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 payor prices with respect to a CDLT.

Data Collection and Reporting

In the proposed rule, CMS proposed that private payor rates be collected over a 12-month period. In the final rule, CMS responded to public comments by adopting a 6-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 payor rates for ADLTs will occur on the same schedule except it will be on an annual basis.

Advanced Diagnostic Laboratory Tests (ADLTs)

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

CMS proposed under the first criterion that an ADLT must be an analysis of RNA or DNA and may include proteins, but protein-only tests would not be considered to be ADLTs. For the final rule, CMS responded to public comments and will also include tests that are solely an analysis of proteins as ADLTs. CMS also proposed under the first criterion 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 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. CMS retained these provisions in the final rule.

Under the second criterion, CMS also proposed that an ADLT is a test cleared or approved by the FDA. CMS did not make any changes from the proposed rule to the final rule as to what it means to be cleared or approved by the FDA. CMS did not establish any additional criteria under the third criterion.

The statute states that new ADLTs will be paid using their actual list charge amount during a new ADLT initial period, which the statute defines as an "initial period of three quarters." Under the final rule, the new ADLT initial period will begin on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage decision for the test is made or the date ADLT status is granted by CMS. The final rule defines the actual list charge as "the publicly available rate on the first day the new ADLT is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been

performed on that date." Once the new ADLT initial period is over, payment for a new ADLT will be based on the weighted median private payor rate paid to the single laboratory and reported to CMS.

Private Payor Defined

PAMA defines the term "private payor" as:

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

The final rule incorporates this statutory definition.

Schedule for Implementation

Under the final rule, CMS is adopting the following schedule for implementation of section 1834A of the Act (created by section 216(a) of PAMA):

- First data collection period for determining calendar year (CY) 2018 CLFS payment rates: January 1, 2016 through June 30, 2016.
- First data reporting period for reporting entities to report private payor 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 payor 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.

Coding of Tests

Healthcare Common Procedure Coding System (HCPCS) codes are created by the American Medical Association (AMA) and CMS. The AMA creates Current Procedural Terminology (CPT) codes that are used primarily to identify medical services and procedures furnished by physicians, suppliers, and other health care professionals. CMS creates HCPCS level II codes for products, supplies, and services not included in the CPT codes. PAMA requires the Secretary to adopt temporary HCPCS codes to identify new ADLTs and new CDLTs (that are not ADLTs) that are cleared or approved by the FDA. PAMA also requires the Secretary to assign a unique HCPCS code for existing ADLTs and existing CDLTs that are cleared or approved by the FDA if they have not already been assigned a unique HCPCS code, and to publicly report the payment rate for the test. The AMA is creating a new coding process specifically to meet the requirements of PAMA. Either the AMA will create CPT Panel codes or CMS will create HCPCS level II codes to identify

new and existing ADLTs and new and existing CDLTs (that are not ADLTs) that are cleared or approved by the FDA under the provisions of the final rule.

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 payor 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 payor 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.

- 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 payor rates for the test.

Expert Advisory Panel

PAMA requires the Secretary to consult with an expert outside advisory panel to provide input on the establishment of payment rates for new CDLTs, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test, and the factors to be used in determining coverage and payment processes for new tests. This advisory panel must include an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in clinical laboratory science or health economics, or in issues related to CDLTs, which may include the development, validation, performance, and application of such tests. The advisory panel may provide recommendations to the Secretary and must comply with the requirements of the Federal Advisory Committee Act (5 U.S.C. App.). A notice announcing the establishment of the Advisory Panel on CDLTs and soliciting nominations for members was published in the October 27, 2014 **Federal Register** (79 FR 63919 through 63920). The panel's first public meeting was held on August 26, 2015. Information regarding the Advisory Panel on CDLTs is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html

Additional Resources

To see the press release for the final rule, click here: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-06-17.html

###

Get CMS news at cms.gov/newsroom, sign up for CMS news via email, and follow CMS on Twitter @CMSgov