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Centers for Medicare & Medicaid Services
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FACT SHEET

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Medicare Clinical Diagnostic Laboratory Tests Payment System Proposed Rule

Overview

Section 216 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 and coverage methodologies for clinical laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS). Under section 1834A, applicable laboratories will be required to report private payor payment rates and corresponding volumes of tests. The statutorily required collection of private payor rates for laboratory tests from applicable laboratories will be the basis for the revised payment rates for most laboratory tests on the CLFS beginning in January 2017.

Background

Medicare pays for clinical diagnostic laboratory tests (CDLT) under the CLFS. The CLFS provides payment for approximately 1,300 CDLTs and Medicare pays approximately $8 billion per year for these tests.

The CLFS was first adopted in 1984, and payment rates were based on charges to the Medicare program. CLFS rates have only been updated since that time to establish payment for new tests or to make statutory, across-the-board updates to the CLFS.

Payment for a new test code on the CLFS established after 1984 is based on either crosswalking, where an existing test(s) with similar methodology and resources is used as a basis for the payment amount, or gapfilling, where a test with no similar methodology is tasked to the Medicare Administrative Contractors to develop a payment amount.

In general, the payment amount for a test on the CLFS furnished on or after January 1, 2017, will be equal to the weighted median of private payor rates determined for the test, based on data collected by applicable laboratories during a specified data collection period and reported to CMS during a specified

data reporting period. In addition, a subset of tests on the CLFS, advanced diagnostic laboratory tests (ADLTs), will have different data collection, reporting, and payment policies associated with them.

Definition of "Applicable Laboratory" and Reporting Requirements

PAMA defines applicable laboratories subject to the new reporting requirements as having their majority of Medicare revenues paid under the CLFS or the Physician Fee Schedule (PFS). For an entity that is composed of multiple facilities, at least one of which is a laboratory that meets the CLIA definition of laboratory, CMS would consider that organization to be an applicable laboratory as long as more than 50 percent of the total Medicare revenues of its entire organization are received from payments under the CLFS and PFS. In other words, the determination of whether an entity meets the more than 50 percent threshold would be made across the entire entity, including all component National Provider Identifier (NPI) entities, and not just those NPI entities that are laboratories.

PAMA also gives CMS the authority to develop a low volume or low expenditure threshold in designating which entities are applicable laboratories. CMS proposes to exclude all laboratories from being an applicable laboratory, and thus from reporting private payor data, if they are paid less than $50,000/year on the CLFS.

We do not expect hospital laboratories to meet the definition of an applicable laboratory, and we estimate that more than 50 percent of independent laboratories and more than 90 percent of physician offices will be precluded from reporting private payor data under the low expenditure criterion. Even though the more than 50 percent threshold and low expenditure threshold would substantially reduce the number of physician offices and independent laboratories that would report private payor rates, we estimate those physicians and laboratories that would be required to report account for 96 percent of CLFS spending on physician office laboratories and more than 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 proposing that the applicable laboratory will be the TIN-level entity, as opposed to the NPI-level entity and that the TIN-level entity will report for all of its NPI-level components.

The statute provides for civil monetary penalties of up to $10,000 per day for each failure to report and/or each misrepresentation or omission in reporting private payor prices with respect to a CDLT.

Advanced Diagnostic Laboratory Test

An ADLT is a laboratory test that is covered under Medicare Part B and that is offered and furnished only by a single laboratory, 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 is proposing that a test qualifying as an ADLT under the first criterion: (i) must be a molecular pathology analysis of multiple biomarkers of DNA or RNA; (ii) when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy or therapies; (iii) provides new clinical diagnostic

information that cannot be obtained from any other test or combination of tests; and (iv) may include other assays. CMS is proposing to require that laboratories submit documentation to support their application.

In the proposed rule, CMS indicates what it means to be cleared or approved by the FDA. We are not proposing any additional criteria that a test would have to meet to be considered an ADLT.

New ADLTs will be paid using their actual list charge amount during an "initial period of three quarters." CMS is proposing that actual list charge would be defined 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 new ADLTs would be based on the weighted median private payor rate reported by the single laboratory that performs the new ADLT.

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)).

Schedule for Implementation

Below is the proposed schedule for CMS's implementation of Section 216 of PAMA:

- First data collection period for determining calendar year CY 2017 CLFS payment rates – July 1, 2015 through December 31, 2015;
- First data reporting period for applicable laboratories to report applicable information to CMS for determining CY 2017 CLFS payment rates – January 1, 2016 through March 31, 2016;
- Annual laboratory public meeting for new tests. CMS would use crosswalking or gapfilling to set rates for new tests (that are not new ADLTs) for which there is no private payor data collected – mid-July 2016;
- CMS publishes the preliminary gapfilled/crosswalked rates for CY 2017 – early September 2016. The public has approximately 30 days, through early October 2016, to submit comments on the preliminary CY 2017 rates.
- CMS makes final CY 2017 CLFS fee rates available on the CMS website – November 1, 2016;
- Statutory implementation date of new CLFS – January 1, 2017.

Coding of Tests

Healthcare Common Procedure Coding System (HCPCS) codes are created by the American Medical Association (AMA) and CMS. The AMA creates 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(s). CMS proposes to create G codes to identify new and existing ADLTs and new and existing CDLTs (that are not ADLTs) that are cleared or approved by the FDA. G codes are temporary HCPCS

level II codes used by CMS to identify professional health care procedures and services, including laboratory tests, that would otherwise be identified by a CPT code, but for which there is no CPT code.

Payment Reduction

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 (2017-2019), and not more than 15 percent for the subsequent three years (2020-2022).

The following is an example of how CMS proposes to implement this requirement:

- If an existing test under the CLFS for CY 2016 has a payment rate of $20.00, but the weighted median private payor rate calculated during CY 2016 (using July 1, 2015, through December 31, 2015 data) produces a payment rate of $15.00, then for CY 2017, the CLFS payment rate for the test becomes $18.00 ($20.00-$2.00), the maximum 10 percent reduction from the current prices.

- The following year, a 10 percent reduction would equal $1.80, lowering the total payment to $16.20.

- The maximum reduction percentage under the statute is applied to the prior year's payment until the reduction becomes less than the applicable percentage (10 percent or 15 percent) and the fee schedule payment goes to the weighted median of the private payor rates for the test.

Additional Resource

For a link to the press release, click here.

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