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National Provider Call

Overview of CMS-1621-P Medicare Clinical Diagnostic Laboratory Test Payment System Proposed Rule

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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Agenda

1. Overview of Proposed Policies Regarding CMS-1621-P

2. Overview of Data Collection System

Current Medicare Clinical Laboratory Fee Schedule (CLFS)

- The CLFS was first adopted in 1984.
- Payment rates were originally based on charge data.
- The CLFS is updated annually to establish payment amounts for new tests and/or statutory across-the-board updates to the fee schedule.
- Payment for a new test code on the CLFS established after 1984 is based on either crosswalking or gapfilling methodologies (42 CFR 414.508).

New CLFS Requirements

- On September 25, 2015 CMS announced its proposal to implement section 216 of the Protecting Access to Medicare Act of 2014 (PAMA; enacted April 1, 2014).
- Requires “applicable laboratories” to report the payment rates that private insurers pay for lab tests and the volume of tests associated with each payment rate.
- Medicare payment amounts for clinical diagnostic laboratory tests will be based on this data beginning January 1, 2017.
- CMS will solicit public comments on the proposed rule until November 24, 2015.

Definition of Applicable Laboratory

- PAMA defines laboratories subject to the new reporting requirements ("an applicable laboratory") as having the majority of its Medicare revenues paid under the CLFS or the Physician Fee Schedule (PFS).
- CMS proposed to use the CLIA definition of laboratory at §493.2 for defining a laboratory.
- CMS proposed to define a laboratory as any entity with at least one facility performing laboratory testing and meeting the CLIA definition.
- CMS proposed to rely on the Tax Identification Number (TIN) as a mechanism for defining the entity required to submit payment data.

Majority of Revenues

- More than 50 percent of the total Medicare revenues of the entire organization, are from the CLFS and PFS.

- Entities must look at their entire organization, including all component NPI entities, in determining whether they meet the 50 percent threshold for total Medicare revenues from the CLFS or PFS.

Low Expenditure Threshold

- Excludes all entities that receive less than $50,000 per year from the CLFS from definition of applicable laboratory.

- Entities must look at their entire organization, including all component NPI entities, in determining whether they meet the $50,000 per year threshold for expenditures from the CLFS.

Applicable Information

- Applicable laboratories must report to CMS all private payor rates and the associated volume for each test.*

- 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)).

- Includes ALL payment rates (even if more than one payment rate for the same private payor for the same test, or more than one payment rate from different payors for the same test).

**Note: An excluded entity (that is, an entity that does not meet the "majority of revenues" or expenditure threshold) would not be permitted to report applicable information to CMS.*

Frequency of Data Collection and Reporting

- For most clinical diagnostic laboratory tests, every three years.
- For advanced diagnostic laboratory tests (ADLTs) annually.*

**ADLTs are discussed later in the presentation.*

Data Collection and Reporting Periods

- Initial Data Collection July 1-December 31, 2015.
- Afterwards, data collection period will be a full calendar year.
- Data Reporting Period will be 3 full months immediately after every Data Collection Period.

New CLFS Payment Methodology

- Using applicable information CMS will calculate a weighted median private payor rate for each test.
- Weighted median becomes the new CLFS payment rate.

Payment Methodology When No Data Are Received for a Test

If CMS receives no applicable information for a given CDLT or ADLT; CMS would use crosswalking or gapfilling to price the test.

ADLTs

Craig Dobyski

Definition of ADLT - Statutory Requirements

Part 1
- Clinical diagnostic laboratory test covered under Medicare Part B.
- Offered and furnished by a single laboratory.
- For use only by original developing laboratory (or successor owner).

Part 2
- Meets one of the following criteria:

(A) 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.

(B) The test is cleared or approved by the FDA.

(C) The test meets other similar criteria established by the Secretary.

Definition of ADLT (Continued)

CMS Proposal for Criterion A

- Must be a molecular pathology analysis of multiple biomarkers of DNA or RNA.
- Predicts development of a certain condition(s) or response to a particular therapy(ies).
- Provides new clinical information.
- May include other assays.

Criterion B - FDA Clearance or Approval

- Premarket Notification Submission (used to demonstrate substantial equivalence).
- Premarket Approval Application (used to demonstrate safety and effectiveness).

Criterion C - Other Criteria

- Not proposing additional criteria at this time.

New ADLTs Vs. Existing ADLTs

New ADLT

- Payment not made under the CLFS prior to January 1, 2017.

Existing ADLT

- Paid for under the CLFS prior to January 1, 2017.

New ADLT Initial Period

Duration of New ADLT Initial Period

- Three full calendar quarters.

Start of New ADLT Initial Period

- Begins first day of the first full calendar quarter following the first day a new ADLT is performed.

Example: If an ADLT is first performed on February 15, the new ADLT initial period would begin on April 1 and end December 31.

Payment for New ADLTs

Prior to New ADLT Initial Period

- MACs would determine payment amount for the test.

During New ADLT Initial Period

- Payment amount is actual list charge for the test.

After New ADLT Initial Period

- Payment amount based on weighted median private payor rate.

Payment for Existing ADLTs

- Prior to January 1, 2017, existing ADLTs paid based on crosswalking or gapfilling.
- Beginning January 1, 2017 payment based on weighted median private payor rate.

ADLT Recoupment Provision

- PAMA requires recoupment of payments when actual list charge substantially exceeds private payor rates.
- Applies when actual list charge is greater than 130 percent of the weighted median private payor rate calculated during the new ADLT initial period.
- CMS would recoup the entire difference between the actual list charge and the median private payor rate.

ADLT Data Collection and Reporting

New ADLTs During New ADLT Initial Period

- Private payor data collected and reported by the last day of second full calendar quarter.

Example: For a new ADLT initial period starting Q2 of 2017 (April 1, 2017) and ending last day Q4 of 2017 (December 31, 2017); the applicable laboratory would be required to report private payor data for the new ADLT by the end of Q3 of 2017 (September 30, 2017).

Existing ADLTs and New ADLTs After New ADLT Initial Period

- Private payor data collected annually on a calendar year basis.
- Reported to CMS during the data reporting period (January 1 through March 31).

Other Provisions

Sarah Harding

Coding under PAMA

Background

- The AMA creates CPT codes that are used primarily to identify medical services and procedures furnished by physicians, suppliers, and other health care professionals (including laboratory tests).
- CMS creates HCPCS level II codes for products, supplies, and services not included in the CPT codes.

Statutory Requirement

- PAMA requires temporary HCPCS codes to identify new and existing ADLTs and new and existing CDLTs (that are not ADLTs) that are cleared or approved by the FDA.

CMS Proposal

- Use G codes for new and existing ADLTs as well as new and existing CDLTs (that are not ADLTs) that are cleared or approved by the FDA.

Limitation on Payment Reduction for Existing Laboratory Tests

Statutory Requirements

- Limits reduction of the payment amount for existing tests (as compared to the payment amount for the preceding year).
- First three years after implementation (CY 2017 through CY 2019), statue limits the reduction to 10 percent.
- For the following three years (CY 2020 through CY 2022) reduction is limited to 15 percent.

CMS Proposal for Limitation of Payment Reduction

- Apply phased-in payment reduction limit per year for existing tests paid under the CLFS prior to 1/1/2017.
- Baseline Payment Amount: The 2016 national limitation amount (NLA) for the existing test.
- To determine the application of the phased-in payment reduction limit for a test, the weighted median private payor rate calculated for CY 2017 would be compared to the CY 2016 NLA.

Confidentiality

- CMS and its contractors may not disclose reported applicable information in a form that would identify:
  - A specific private payor or laboratory;
  - Prices charged or payments made to a laboratory.
- Exception: As CMS determines necessary to implement section 1834A of the Act and to permit the Comptroller General, the Director of the CBO, the HHS OIG, the MedPAC, or other law enforcement entities such as the Department of Justice to review the information.

Data Collection System

Sarah Harding

Fee for Service Data Collection System

- Web Based data collection system available to applicable laboratories.

- Ability to collect all applicable information:
  - Upload .csv file;
  - Manual Data Entry

EIDM Registration

- Enterprise Identity Management
- Register Early

Resources

- CMS press release
- Fact Sheet
- Proposed Rule (CMS-1621-P)
- CLFS Website

Acronyms in this Presentation

ADLT	Advanced Diagnostic Laboratory Test
AMA	American Medical Association
CBO	Congressional Budget Office
CDLT	Clinical Diagnostic Laboratory Test
CLFS	Clinical Laboratory Fee Schedule
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
CPT	AMA's Current Procedural Terminology
DNA	Deoxyribonucleic Acid
EIDM	Enterprise Identification Management
FDA	Food and Drug Administration
HHS	Health and Human Services
MAC	Medicare Administrative Contractor
MedCAC	Medicare Evidence Development and Coverage Advisory Committee
NLA	National Limitation Amount
NPI	National Provider Identifier
OIG	Office of Inspector General
PAMA	Protecting Access to Medicare Act of 2014
PFS	Physician Fee Schedule
RNA	Ribonucleic Acid

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