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ALERT

Health Care

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CMS Issues Final Rule on Overhaul of Clinical Diagnostic Laboratory Test Payment System

On June 17, 2016, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule (the "Final Rule") that makes significant changes to Medicare reimbursement for clinical diagnostic laboratory tests ("CDLTs"). Implementing the mandate of the Protecting Access to Medicare Act of 2014 ("PAMA"), the Final Rule ties payment for CDLTs to rates paid by private payors.

Starting on January 1, 2018, Medicare payment for most CDLTs will be set at the weighted median of private payor rates, based on laboratory-reported data. For the type of CDLTs known as Advanced Diagnostic Laboratory Tests, new rates based on private payor rates will be implemented according to an alternate process and timeline.

Implementation of the Final Rule will impose on laboratories substantial data collection and reporting obligations and may result in significant reductions in payment.

Highlights

- The Final Rule changes how Medicare payment rates are set for CDLTs paid under the Clinical Laboratory Fee Schedule ("CLFS"). Medicare will use private payor data, reported to it by certain laboratories, to establish new rates. For most CDLTs, the new rates will be effective for tests paid under the CLFS on and after January 1, 2018 (rather than January 1, 2017, as proposed).
- The Final Rule refines the subcategory of CDLTs created under PAMA called Advanced Diagnostic Laboratory Tests ("ADLTs"), and details the unique methodologies by which initial ADLT reimbursement rates will be set. An ADLT is defined as a CDLT covered under Medicare Part B that is furnished by a single laboratory and either (i) is a CMS-approved analysis of multiple biomarkers of DNA, RNA, or proteins, or (ii) is cleared or approved by the Food and Drug Administration ("FDA").
- The Final Rule identifies those laboratories that must report private payor information to CMS for purposes of Medicare rate-setting as "applicable laboratories." An applicable laboratory is defined as any laboratory that (i) bills Medicare Part B under its own National Provider Identifier ("NPI") number, (ii) receives more than 50% of its Medicare revenue under the CLFS or the Physician Fee Schedule ("PFS"), and (iii) either (a) has Medicare CLFS revenue exceeding $12,500 during the six-month data collection period, or (b) furnishes an ADLT. By setting the threshold amount of Medicare revenue at $12,500, CMS effectively excludes many physician office laboratories and some independent laboratories from the data collection and reporting obligations.
- The Final Rule imposes reporting burdens by Taxpayer Identification Number ("TIN"), and, therefore, entities that have multiple NPI numbers organized under a single TIN will report as a single unit.
- The Final Rule specifies the type of data that must be reported (private payor rates, testing volume at each rate, and the Healthcare Common Procedure Coding System ("HCPCS") code associated with each test), shortens the data collection period from one year in the proposed rule to six months in the Final Rule, and specifies when data must be reported to CMS.

What Is the New Subset of CDLTs Known as ADLTs?

An ADLT is a type of CDLT. Under the Final Rule, to achieve designation as an ADLT, a test must be reimbursable under Medicare Part B as a CDLT, offered and furnished by a single laboratory, and not sold for use by any laboratory other than the original developing laboratory (or successor owner). In addition, the test must be either:

1. An analysis of multiple biomarkers of DNA, RNA, or proteins, combined with a unique algorithm to yield a single patient-specific result; or

2. Cleared or approved by the FDA.

Although CMS had proposed to exclude from the definition of ADLTs tests that evaluate only proteins, CMS opted to include protein-only tests in the Final Rule.

In addition, CMS distinguished between "existing ADLTs" and "new ADLTs." Existing ADLTs are those ADLTs paid for under the CLFS between April 1, 2014 (the enactment date of PAMA) and December 31, 2017, and "new ADLTs" are those ADLTs for which payment has not been made under the CLFS prior to January 1, 2018. These categorizations are relevant for rate-setting.

In the preamble to the Final Rule, CMS indicated that it will issue additional guidelines to assist laboratories seeking to apply for ADLT status.

Who Must Collect and Report Private Payor Information?

Under the Final Rule, CMS defines "applicable laboratories" subject to data collection and reporting obligations broadly to include hospital outreach laboratories, independent laboratories, and physician office laboratories meeting specific revenue thresholds. More specifically, a laboratory must collect and report data under the Final Rule if it bills Medicare Part B under its own NPI number and receives more than 50% of its total Medicare revenue through CLFS and PFS reimbursement (with at least $12,500 in CLFS revenue during a six-month data collection period). The $12,500 threshold does not, however, apply to laboratories that furnish ADLTs; that is, regardless of whether its revenue is below $12,500, a laboratory that furnishes an ADLT must comply with the Final Rule's collection and reporting obligations if it otherwise constitutes an "applicable laboratory" under the Final Rule. CMS believes the "low expenditure" threshold of $12,500 will exclude the majority of physician office laboratories and many independent laboratories from the collection and reporting obligations.

What Information Must Be Reported and When?

Under the Final Rule, "applicable information" that must be reported includes the private payor rates paid for each test during the data collection period, the volume of tests performed at each rate, and the HCPCS code assigned to the test. CMS defines "private payor" broadly to include health insurers, group health plans, Medicare Advantage plans, and Medicaid managed care organizations. In addition, CMS clarified that the private payor rate is the final amount paid by the private payor after all discounts are applied and patient cost-sharing amounts are deducted.

For CDLTs that are not new ADLTs (*i.e.*, for non-ADLTs and for existing ADLTs), data must be collected over a six-month period between January 1 and June 30 of the collection year and reported to CMS between January 1 and March 31 of the following year. So that new rates may be put into effect on January 1, 2018, the first data collection period for these tests is the six-month period between January 1, 2016 and June 30, 2016. Correspondingly, the first data reporting period is between January 1, 2017 and March 31, 2017. Thereafter, the data collection and reporting period for CDLTs that are not ADLTs will repeat every three years. By contrast, the data collection and reporting cycle for ADLTs will repeat every year.

New ADLTs will commence the data collection and reporting process on a rolling basis during the test's "initial period." The initial period is test-specific and is the nine-month period beginning on the first day of the first full calendar quarter following the later of (i) the date a Medicare Part B coverage determination for the ADLT is made, or (ii) the date that ADLT status is affirmatively granted by CMS. The ADLT laboratory must collect applicable information during, and report applicable information by the end of, the first six months of the ADLT's initial period. CMS will use this information to generate a new rate based on private payor rates, which will go into effect at the end of the test's initial period. After the test's initial period, the laboratory will adopt the annual data collection and reporting schedule for existing ADLTs, *i.e.*, it will report applicable information during a three-month period each year.

CMS is expected to provide further details through sub-regulatory guidance as to the form and format of reporting for all CDLTs.

What Will Happen to Payment Rates for CDLTs and ADLTs?

PAMA and its implementing regulations are designed to revise the methodology by which CDLTs are reimbursed under Medicare so that reimbursement rates for CDLTs more closely align with market rates. To that end, the Final Rule establishes a process by which reimbursement rates for existing CDLTs will be evaluated, revised and implemented, and a process by which reimbursement rates for new CDLTs will be determined. The process and timing by which these changes will occur vary somewhat depending on the nature of the test, when it was first added to the CLFS and whether applicable information exists for collection and reporting purposes.

In general, the payment rate for CDLTs furnished on or after January 1, 2018 will be the weighted median of private payor rates collected for the test during the most recent data collection period. Under this methodology, payment rates for CDLTs generally are expected to be reduced.

For purposes of implementing these rate changes, any CDLT that is assigned a new or substantially revised code on or after January 1, 2005 is a new CDLT. For new CDLTs for which applicable information exists, a new payment rate reflecting private payor rates will go into effect as of January 1, 2018. For any new CDLT for which there is insufficient information to establish a payment amount reflecting private payor rates, payment as of January 1, 2018 will be based on cross-walking and gap-filling methodologies described in the regulations (until applicable information is available).

For CDLTs that are not new CDLTs, the payment rate reflecting private payor rates will be established as of January 1, 2018, but implemented over time. Specifically, reductions in payment will be phased in over six years, rather than all at once, with the maximum reduction in Medicare payment set at 10% for each of the first three years and at 15% for each of the last three years.

Once set, the revised payment rate for CDLTs that are not ADLTs will be in effect for a period of three calendar years (aligning with the data reporting periods) and not subject to any further adjustment (including any geographic adjustment, budget neutrality adjustment, or annual update).

The Final Rule's application to ADLTs differs somewhat. As noted above, the Final Rule distinguishes between existing ADLTs and new ADLTs. ADLTs that are first reimbursed under the CLFS between April 1, 2014 and December 31, 2017 (the "transition period") are considered existing ADLTs. During this transition period, CMS will reimburse existing ADLTs according to the methodologies for pricing, coding and coverage in effect the day before PAMA's enactment, namely cross-walking and gap-filling. Beginning January 1, 2018, CMS will set the rate for existing ADLTs based on the weighted median of private payor rates reported for these tests when applicable information is available.

With respect to new ADLTs, payment during the ADLT initial period will be the test's "actual list charge" as attested to by the laboratory. Following the initial period, the test will no longer be considered a "new ADLT" and payment will be based on the weighted median of private payor rates collected during the applicable data collection period. Significantly, if the actual list charge at which the ADLT is reimbursed during the initial period is more than 130% of the revised weighted median rate, CMS will recoup the difference from the laboratory.

Once set, the revised payment rate for ADLTs will be in effect for a period of one calendar year.

What if a Laboratory Reports Inaccurate or Misleading Information?

The Final Rule requires the President, Chief Executive Officer, or Chief Financial Officer of the reporting entity or their delegate to certify to the accuracy of the data reported. The reporting entity will be subject to civil monetary penalty liability for failing to report applicable information or making a misrepresentation or omission related to the reporting. PAMA provides for civil monetary penalties of up to $10,000 per day for each failure to report or misrepresentation or omission in reporting applicable information.

How Does This Affect the Local Coverage Determination Process?

Under PAMA, CMS is authorized to designate between one and four Medicare Administrative Contractors ("MACs") to establish coverage policies and process claims for CDLTs. In the Final Rule, CMS stated that it believes this authorizes the agency to reduce the number of MACs issuing local coverage determinations (or "LCDs") for CDLTs, resulting in fewer MACs issuing LCDs for larger geographic areas. However, CMS declined to make any changes to current development and implementation of LCDs or claims processing functions, citing the significant increase in complexity to programmatic and operational issues that would result from such changes.

Conclusion

The Final Rule dramatically changes the payment method for CDLTs and ADLTs under the CLFS. Beginning January 1, 2018, CMS will phase in new payment rates that are based on private payor data reported mostly by independent and hospital outreach laboratories.

Laboratories furnishing or developing CDLTs that meet the ADLT criteria will need to apply for ADLT status separately from Part B coverage. CMS will provide additional guidance on the process by which ADLT status may be obtained. Although new ADLTs will initially be reimbursed at their actual list charge, laboratories could be subject to later recoupment should the actual list charge for the test be greater than 130% of the later-determined weighted median of private payor rates.

The Final Rule also imposes significant data collection and reporting obligations on laboratories that will require administrative, financial and operational resources to ensure accuracy and completeness.

Should you have questions regarding the Final Rule, please contact your usual Ropes & Gray advisor.