Changes To Medicare Payment For Clinical Lab Tests:
Part 2 —By Paul M. Rudolf, Thomas A. Gustafson, Jennifer B. Madsen and Amanda Cassidy, Arnold & Porter LLP

Law360, New York (October 16, 2015, 1:49 PM ET) -- On Sept. 25, 2015, the Centers for Medicare and Medicaid Services released a proposed regulation that describes the agency’s plan for implementing Section 216 of the Protecting Access to Medicare Act. PAMA makes significant changes to Medicare’s payment rates to clinical laboratories on the Clinical Lab Fee Schedule (“CLFS”). It requires applicable laboratories, a set of laboratories defined in the proposed rule, to report to the federal government information on the payments they receive from private payers for tests on the CLFS. CMS will use the private payer data to calculate a weighted median payment for each test, which will replace Medicare’s current CLFS rates beginning Jan. 1, 2017. For most tests, clinical laboratories will report private payer information every three years, and CMS will update those CLFS rates accordingly. However, for a subset of molecular diagnostic tests called Advanced Diagnostic Laboratory Tests (“ADLTs”), sponsors would report data on private payer rates, and Medicare payment would be updated, every year.

Proposed Schedule for Initial Implementation

<table>
<thead>
<tr>
<th>Step</th>
<th>Timing</th>
</tr>
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<tbody>
<tr>
<td>“Data collection period” — Information on laboratory services delivered during this period will be reported and reflected in rate setting</td>
<td>July 1 to December 31, 2015</td>
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<tr>
<td>“Data reporting period” — during which laboratories will report data to CMS</td>
<td>January 1 to March 31, 2016</td>
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<tr>
<td>CMS will develop new rates</td>
<td>April 1 to November 2016</td>
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<tr>
<td>CMS will publish new rates</td>
<td>November 2016</td>
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<tr>
<td>New rates go into effect</td>
<td>January 1, 2017</td>
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CMS suggests that it may make available preliminary rates for comment in September 2016, but it does not discuss this possibility in any detail.

Under the new system, Medicare’s payments for clinical diagnostic laboratory tests (“CDLTs”) will be tied to rates paid by private insurers and Medicare and Medicaid managed care plans, rather than to providers’ costs (which are used as inputs to determine Medicare payment rates for most other health care services). It is generally expected that Medicare payment rates for CDLTs, which, under pre-PAMA law, are generally static and based on outdated cost data, will fall over time because private payer rates are determined by competition among laboratories and reflect current cost and resource requirements as well as economies of scale. It is also believed that some laboratories may have been able to negotiate favorable payment rates from private payers based on the value of their tests. For example, some molecular diagnostic tests (e.g., detection of genetic mutations) have the potential to result in lower downstream health care costs by helping doctors choose the most effective treatments for each patient and avoiding the cost of therapies likely to be ineffective.

The intent of the law is to achieve savings for Medicare without creating disincentives for the development of innovative tests that can improve care. CMS estimates that Medicare spending
on CLFS services would decrease by $360 million in fiscal year 2017, a cut of 4.5 percent.

This proposed rule is significantly delayed, as the statute required CMS to release a final rule implementing the data reporting requirements of PAMA by June 30, 2015. The proposed rule was published in the Federal Register on Oct. 1, and comments will be accepted from stakeholders until Nov. 24.

The delay in establishing the data collection and reporting parameters has created an awkward schedule; for example, CMS proposes a data collection period that started on July 1, 2015, well before the proposed rule was released. The scheduling constraints are likely to lead to pressures on CMS to delay both the collection and reporting requirements and, ultimately, the rates that would be set based on the reported data.

Below we describe provisions of the proposed rule that affect ADLTs in greater detail and identify open issues and potential concerns for the industry. More details on the reporting requirements may be found in the first Law360 article of this series.

**Definition of ADLT and Pathways for ADLT Designation**

PAMA includes special provisions for ADLTs. The statute defines an ADLT as a CDLT covered under Medicare Part B that is marketed and performed only by a single laboratory or its successor owner and not sold for use by a laboratory other than the laboratory that designed the test and that meets the following criteria:

1. is an analysis of multiple biomarkers of DNA, RNA or proteins combined with a unique algorithm to yield a single patient-specific result;
2. is cleared or approved by the U.S. Food and Drug Administration; or
3. the test meets other similar criteria established by the secretary.

CMS proposes definitions of some of the elements of an ADLT and adds requirements that would limit the types of tests that could theoretically qualify under (1) above.

**Single Laboratory**

CMS proposes to define a “single laboratory” as a facility with a single CLIA certificate since, “We view the statute as intending to award special payment status to the one laboratory that is expending the resources for all aspects of the test — developing it, marketing it to the public, performing it, and selling it.”[1] CMS proposes to define a “successor owner” as “a single laboratory that has assumed ownership of the laboratory that designed the test” that meets specific criteria.[2] By limiting the “single laboratory” and its “successor owner” to a single CLIA certificate, the proposed rule appears to prevent an entity with several CLIA certificates, such as the campus of an academic medical center, from receiving ADLT status for its tests.

CMS expects laboratories that receive ADLT status for their tests to document changes in ownership. The agency expects to monitor compliance by confirming that: (1) applicable information for an ADLT is reported by only one applicable laboratory and (2) that each applicable laboratory that reports applicable information for an ADLT has a single CLIA certificate.

In addition to being performed by a single laboratory or its successor owner, an ADLT must
meet the criteria of one of two pathways: (1) the non-FDA pathway or (2) the FDA pathway.

**Non-FDA Pathway**

To be designated as an ADLT under the non-FDA pathway (i.e., the pathway for tests that have not been approved or cleared by the FDA), CMS proposes that the test must meet certain requirements. Under the non-FDA pathway, a test must analyze multiple biomarkers of DNA or RNA, which could consist of one test that analyzes multiple biomarkers or of multiple tests that each analyze one or more biomarkers. Under CMS' proposal, an ADLT could also, but is not required to, include assays that analyze proteins.

The test’s information on DNA or RNA must be “combined with a unique algorithm to yield a single patient-specific result.” CMS proposes that the algorithm must be empirically derived. The test must also provide new clinical diagnostic information that cannot be obtained from any other existing test on the market or combination of tests. The decision as to whether a test provides new clinical diagnostic information that cannot be obtained elsewhere would be made by CMS. Therefore, it appears that no “me too” tests would qualify as an ADLT under the non-FDA pathway.

**FDA Pathway**

Tests approved by the FDA under a pre-market approval application or cleared under Section 510(k) of the Food, Drug and Cosmetic Act could be considered ADLTs under the FDA pathway. CMS notes that FDA regulations exempt certain low-risk devices from approval or clearance, and CMS does not intend for this criterion to cover any devices exempt from FDA approval or clearance.

**Application for ADLT Status**

Laboratories that wish to receive ADLT status must apply to CMS. The agency plans to establish guidelines for laboratories to apply for ADLT status and submit documentation to support their application. This process will be outlined through subregulatory guidance. A laboratory seeking new ADLT status for its test will have to attest to the actual list charge and the date the new ADLT is first performed and laboratories using pathway (ii) would have to submit documentation of their FDA clearance or approval for the test. However, the proposed rule is silent on a number of important aspects of the application process for pathway (i), including the contents of the application and the level of detail requested about the test protocol; the types of medical evidence that should be included in the application; the criteria CMS will use to evaluate ADLTs against the proposed requirements; who will review the application; the ability of applicants to communicate or meet with CMS during this process; and whether there will be a mechanism to appeal denied applications.

**Confidentiality**

CMS says that while the agency does not expect to make information in an ADLT application available to the public, the information is not explicitly protected from disclosure under the confidentiality provisions of the statute, nor is it explicitly protected from disclosure in response to a Freedom of Information Request request. An ADLT applicant “should be aware” that information in an ADLT application may not be protected from public disclosure even if it is marked as confidential and proprietary as the information may be subject to disclosure under FOIA unless, consistent with FOIA exemption (b)(4), the information relates to trade secrets and
commercial or financial information that is exempt from disclosure. The ADLT applicant would need to substantiate this confidentiality by expressly claiming and demonstrating that substantial competitive harm would occur from the disclosure. This issue is especially important for pathway (i) applications.

At this time it is unclear whether either pathway is inherently more attractive than the other; so test developers may need to make decisions about the best pathway on a test-by-test basis. For example, under pathway (i), where the review process appears to be a black box, it is unclear whether the proposed requirement to provide new diagnostic information not otherwise obtainable is really a difficult-to-demonstrate “superiority” requirement, and there are potential confidentiality concerns. On the other hand, under pathway (ii), FDA data requirements and the length and complexity of FDA review could be substantial and may make that pathway less appealing.

Payment for ADLTs

For new ADLTs, that is, ADLTs that have not been paid under the clinical lab fee schedule prior to Jan. 1, 2017, Medicare will pay based on the actual list charge, or the publicly available rate on the first day that the test is available for purchase by a private payer. This rate based on actual list charge will be in effect for the first three full calendar quarters that the test is on the market.

The first day a test is available means the date a test 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. Publicly available rate means the lowest amount charged for an ADLT that is readily accessible in such forums as a company website, test registry or price listing.

Because its payment systems are updated quarterly, CMS proposes that the first day of this three-quarter period will begin on the first day of the next calendar quarter after the first day the test becomes available. For example, if a test becomes available on Feb. 4, the three quarter-period begins on April 1. CMS proposes that the Medicare Administrative Contractor (“MAC”) with jurisdiction over the laboratory will set the payment rate before the three-quarter period begins.

Laboratories performing ADLTs must report private payer payment data not later than the last day of the second full quarter after the first day the test become available. Starting at the beginning of the fourth full calendar quarter, Medicare’s payment rate for the ADLT would be based on the private payer data reported.

Recoupment for Overpayments

If the Medicare payment amount during the new ADLT’s initial three-quarter period (i.e., the rate based on the actual list charge) is more than 130 percent of the Medicare payment amount determined using the weighted median of private payor rates that is applicable after the initial period, CMS will recoup the entire difference between the Medicare payment amounts during the initial period and the Medicare payment amount based on the weighted median of private payor rates.

Payment for New CDLTs That Are Not ADLTs
CMS proposes to define new CDLTs as those tests that are assigned a new or substantially revised Healthcare Common Procedure Coding System ("HCPCS") code and that do not meet the definition of an ADLT. For CDLTs that are assigned a new or substantially revised HCPCS code after the date of enactment of PAMA until private payer data is available, payment will be determined in the same manner historically used to set payment rates for new tests; that is, by either crosswalking the new code to the rate established for a comparable existing test or by gap filling the rate for a new code for which there is no comparable test. For gap filling, the following sources of information must be taken into account, if available: (a) charges for the test and routine discounts to changes; (b) resources required to perform the test; (c) payment amounts determined by other payers; (d) charges, payment amounts and resources required for other tests that may be comparable; and (e) other criteria that the secretary determines to be appropriate. The secretary is required to make available to the public an explanation of the payment rate for the test, including an explanation of how those criteria were applied.

Payment for Tests When No Private Payer Payment Data Is Available

Labs that do not meet the definition of an applicable lab would be prohibited from submitting applicable information for the purpose of rate setting. CMS estimates that there are 17 tests whose utilization is completely attributed to laboratories that would not be reporting because they fell below the $50,000 threshold. It is also possible that laboratories that develop new ADLTs could otherwise meet the criteria for an applicable laboratory, but have Medicare revenues of less than $50,000 in a year, and thus exempt from reporting applicable information.

After noting that PAMA is silent on payment for such tests, CMS proposes to make payment for tests for which no private payer data is reported based on crosswalking or gap filling. CMS would use this approach even if private payer data was available for a previous data collection period.

Coding Provisions

PAMA requires that, not later than Jan. 1, 2016, the secretary shall assign a unique HCPCS code and publicly report the payment rate for the test for each existing ADLT and each existing CDLT that is cleared or approved by the FDA for which payment is made as of PAMA’s enactment date (April 1, 2014), if such test has not already been assigned a unique HCPCS code. In this case, CMS proposes to adopt temporary HCPCS Level II codes (G codes) that would be effective for up to two years, until a permanent HCPCS code is established, unless CMS believes it is appropriate to continue to use the G code. The proposed rule is silent on what happens to the coverage and/or payment for the test at the two-year mark if the agency decides not to extend the G code.

CMS is also required to assign a unique identifier for an ADLT or CDLT that is cleared or approved by the FDA if a laboratory or a manufacturer requests one. Currently, the same HCPCS code is used for both FDA-approved laboratory tests and lab-developed tests that detect the same analyte (e.g., KRAS). CMS believes the existing HCPCS coding process would suffice for this process. If a laboratory requests a unique HCPCS code for tracking or monitoring an FDA-approved or cleared test, CMS would assign an HCPCS Level II code.

Both PAMA and the proposed rule appear to be ambiguous with respect to the connection between HCPCS code assignment and payment rate. For example, applicable labs will report payment rates for “tests” by HCPCS code and CMS will establish payment for a “test” based on this reported data. In cases where multiple codes are assigned to tests for the same analyte
(e.g., because some tests are FDA-approved/cleared and others are not, and/or because a lab or manufacturer has requested a unique identifier), aside from the potential for inaccurate reporting due to code confusion, it is unclear whether there is a requirement for CMS to establish different payment rates for codes that describe “tests” for the same analyte.

Issues on which the proposed rule is silent include: (1) How will CMS ensure it identifies all FDA-cleared or approved CLDTs that do not have HCPCS codes?; (2) Will CMS assign a unique HCPCS code to each test for a single analyte or assign a single HCPCS code to all FDA-approved/cleared tests for a single analyte?; (3) How will labs “report” the payment rate for tests that have heretofore not been identifiable?; and (4) Will assignment of a code to an FDA-approved/cleared test, or group of tests, affect the payment rate (e.g., will Medicare establish different payment rates for FDA-regulated tests as opposed to lab-developed tests for the same analyte)?

**Administrative Issues**

**Local Coverage Process**

Starting Jan. 1, 2015, PAMA requires CMS and its MACs, including Palmetto GBA, to issue coverage policies for laboratory tests in accordance with the process established for MAC local coverage determinations (“LCDs”) and for reconsiderations of those decisions. This process includes a public comment period, a 45-day notice period before an LCD takes effect and public meetings. It is likely CMS will receive comments as to how this requirement will affect Palmetto’s MolDx program.

**“Lab MACs”**

The statute gives the secretary the authority to designate up to four MACs to either establish coverage policies or to establish coverage policies and to process claims. CMS does not propose to implement either of these possibilities at this time, but might do so through notice and comment rulemaking in the future. CMS believes that reducing the number of MACs issuing LCDs for CDLTs could be finalized within two to four years but that reducing the number of MACs processing claims for CDLTs would take much longer and involve significantly more complex, programmatic and operational issues, for which CMS would need additional funding.

**What Effect Will PAMA Implementation Have on Regulation of LDTs?**

The FDA has issued controversial draft guidance on the regulation of LDTs, which has spawned a series of counterproposals from affected stakeholders, including draft legislation that would require the FDA to regulate certain LDTs while prohibiting FDA regulation of others.

While it is not possible to do anything but speculate at this time, the extent to which favorable payment under PAMA is facilitated, or inhibited, by obtaining FDA approval or clearance could significantly affect test developers decisions to undergo FDA review, whether required or not, and should be considered in any legislative proposals that would require or prohibit FDA regulation of certain LDTs.

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[2] The criteria are: (1) the removal or addition of a member of a partnership, (2) transfer of title and property of an unincorporated sole proprietorship, (3) merger or consolidation of a corporation or (4) leasing of all or part of the facility that originally developed the test.