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Changes To Medicare Payment For Clinical Lab Tests: Part 1

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Law360, New York (October 15, 2015, 6:12 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. (Stay tuned for more information on ADLTs and on coding for tests in a future Law360 article.)

Step	Timing
"Data collection period" — Information on laboratory services delivered during this period will be reported and reflected in rate setting	July 1 to December 31, 2015
"Data reporting period" during which laboratories will report data to CMS	January 1 to March 31, 2016
CMS will develop new rates	April 1 to November 2016
CMS will publish new rates	November 2016
New rates go into effect	January 1, 2017

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generally expected that Medicare payment rates for CDLTs, which, under pre-PAMA law, are generally static and based on outdated cost data, will fall over time because private payer rates are determined by competition among laboratories and reflect current cost and resource requirements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 in greater detail and identify open issues and potential concerns for the industry.

Definition of Applicable Laboratory

Section 216 of PAMA defines an "applicable laboratory" as one that receives the majority of its Medicare revenue from either the Physician Fee Schedule ("PFS") or the CLFS. The secretary is given authority to establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory, but is not required to do so.

In its proposed regulations defining an applicable laboratory, CMS sought to balance the need for robust data on private payor rates with the burden of reporting. CMS states that it believes "the statute intends to limit reporting primarily to independent laboratories and physician offices (other than those that meet the low expenditure or low volume threshold ...) and not include other entities (such as hospitals, or other health care providers) that do not receive the majority of their revenues from PFS or CLFS services."

CMS proposes to define a "laboratory" as an entity that is a laboratory as defined in regulations under the Clinical Laboratory Improvement Amendments ("CLIA"),[1] but not all CLIA-certified laboratories would be applicable laboratories for reporting purposes. CMS also notes that this definition includes entities that are only laboratories as well as multicomponent entities of which a laboratory is one (e.g., a hospital system). Of the 249,000 entities with a CLIA certificate, about 6,000 are independent laboratories, and 9,000 are hospitals.

CMS proposes to have labs report applicable information by Taxpayer Identification Number ("TIN"). A single TIN may include a single lab, multiple labs and/or other types of providers or suppliers as identified by National Provider Identifiers ("NPIs").[2] Since discounts to laboratories' payment rates are typically negotiated with private payers at the TIN level, CMS believes reporting at the TIN level rather than at the level of the CLIA laboratory would be less burdensome while not risk losing data important for accurate rate calculations.

CMS proposes that only TINs which receive, collectively from all its associated NPI entities/individuals, more than 50 percent of Medicare revenues[3] from either the CLFS or the PFS will be considered applicable laboratories for reporting purposes under PAMA.[4] Hospital labs are typically part of a larger TIN entity that receives the bulk of its Medicare payments under the inpatient and outpatient prospective payment systems; CMS believes that hospital labs would not qualify as applicable labs.[5] An entity could be an applicable lab in one data reporting period but not in the next one, but CMS expects this situation to be rare.

CMS also proposes that an applicable laboratory must have Medicare revenue in excess of a specified threshold to report applicable information under PAMA. CMS proposes that if an applicable lab receives less than $50,000 in Medicare revenue from the CLFS in a calendar year ($25,000 for the initial data collection period from July 1 to Dec. 31, 2015), it would not be required to report applicable information. CMS proposes to determine whether or not a lab is an applicable lab based on all services provided during the data collection period; this means that a lab may not know before the data collection period begins whether or not it is an applicable lab.

According to CMS, establishing a $50,000 threshold for Medicare revenue would substantially reduce the number of entities reporting, without materially affecting the quality and sufficiency of the data needed to set rates. CMS estimates that 94 percent of physician office laboratories and 52 percent of independent laboratories would be excluded by the threshold, while still capturing 96 percent of CLFS spending on physician office laboratories and 99 percent of CLFS spending on independent laboratories.

CMS seeks comments on the definition of an applicable laboratory, as well as on whether data should be reported at a higher level of aggregation (such as a corporate parent TIN on behalf of subsidiary TINs) or at a lower level (e.g., NPI).

Process and Timelines for Reporting and Compliance Monitoring

Data Reporting Requirements for Applicable Laboratories

Applicable laboratories, as defined above, are required to report, during the collection period, applicable information for each CDLT that the laboratory furnishes. The proposed rule defines "applicable information" as: (1) the specific HCPCS code associated with the test; (2) each private payor rate paid for the test; and (3) the associated volume of tests performed corresponding to each private payor rate.

Information about tests for which payment is made on a capitated basis is excluded from the reported data. Labs will report this data every three years for all CLDTs.

The statute defines the data collection period as "a period of time, such as a previous 12-month period, specified by the Secretary." CMS proposes for the data collection period to be the calendar year during which an applicable laboratory collects applicable information and that immediately precedes the data reporting period. CMS proposes an exception to this definition for the first data collection period, which CMS proposes to be the six-month period of July 1, 2015, through Dec. 31, 2015. The proposed rule does not discuss whether the data collected is for services performed during the data collection period or for services for which it receives payment during the data collection period. This is an important distinction, as payment for many tests may not be received for weeks after the service is performed.

CMS proposes to define the data reporting period as the three-month period during which an applicable laboratory reports applicable information to CMS and that immediately follows the data collection period. CMS is silent on whether applicable laboratories must report payment adjustments or recoupments (e.g., based on appeals of denied or allegedly improperly paid claims), which could occur during or after the data reporting period.

CMS proposes to define a private payor as: (1) a health insurance issuer, (2) a group health plan, (3) Medicare Advantage plan and (4) Medicaid managed care organization. A private

payor rate is the amount that was paid by a private payor for a CDLT after all price concessions are applied. These rates include any patient cost-sharing amounts, if applicable. The proposed rule is silent as to how laboratories should allocate single copayments across multiple tests and whether laboratories should report all patient cost-sharing that was due, or only that which was actually paid. The proposed rule also does not address situations where a laboratory is out-of-network for a particular plan and how differences in payment and copayments are to be reflected in the reported data.

Price Concessions

In the proposed rule, CMS notes that the statute lists specific price concessions in Section 1834A(a)(5) of the Act — discounts, rebates and coupons; as well as referencing Section 1847A(c)(3) of the Act, which includes volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates (except for Medicaid rebates under Section 1927 of the Act). The agency notes that these lists are examples of price concessions, and other price concessions that are not described, but that might be applied to the amounts paid by private payers, should be reported also.

Certification by Executives

To certify data integrity, the president, CEO or chief financial officer of an applicable laboratory or an individual with appropriate delegated authority must sign a certification statement that the data provided are accurate, complete and truthful, and meet all the reporting parameters.

Civil Monetary Penalties

If the secretary of the U.S. Department of Health and Human Services determines that an applicable laboratory has failed to report, or made a misrepresentation or omission in reporting, applicable information, then the secretary may apply a civil monetary penalty in an amount of up to $10,000 per day for each failure to report or for each misrepresentation or omission. CMS proposes to implement this provision in a manner similar to the implementation of like provisions regarding CMPs related to reporting of average sales price data by drug manufacturers.

Confidentiality and Disclosure

CMS will not disclose applicable information reported to CMS in a manner that would identify a specific payor or laboratory, or prices charged or payments made to a laboratory. However, the statute permits CMS to disclose data to the comptroller general, the director of the Congressional Budget Office and the Medicare Payment Advisory Commission, and CMS proposes to add the HHS Office of Inspector General and the U.S. Department of Justice to this list on the basis that such disclosure is necessary to administer and enforce the new payment system. The name of an applicable laboratory will be exempt from disclosure under the Freedom of Information Act.

Determination of Medicare Payment Rate

Each test furnished on or after Jan. 1, 2017, will be paid for using the weighted median payment from private payers for the test. CMS will calculate a weighted median for the test, by “arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory.”

Once established, the payment rates for CDLTs will be updated every three years based on the next collection and reporting period. PAMA prohibits any other updates, such as for inflation. These rates also will apply to tests furnished by a hospital laboratory if the test is paid for separately, and not as part of a bundled payment under Section 1833(t).

CMS proposes to publish final payment rates at least 60 days before they are implemented, which would be around Nov. 1, 2016, for rates effective Jan. 1, 2017. CMS does not propose to establish a notice and comment period for "proposed" payment rates but suggests that the tentative rates may be made available in September. In contrast to other payment systems where CMS makes available the data upon which payment rates are established (e.g., claims data), CMS does not propose to make available to the public the laboratory reported private payer payment data that is used to establish payment rates. Therefore, it is unclear whether or how laboratories could validate the calculations used to set the median private payer rates.

Impact on Lab Spending

CMS estimates that the new system will result in aggregate payment reductions of $360 million (or -4.5 percent of total spending under the CLFS) in 2017. Program payments would be reduced by an estimated $2.94 billion, or -7.35 percent, over the first five years, and savings over 10 years are estimated to total $5.14 billion, or -6.43 percent. In comparison, the Congressional Budget Office estimated savings of $2.5 billion over a 10-year period when PAMA was enacted in 2014.[6] CMS does not present estimates on a code-by-code or other disaggregated basis because it lacks data from private payers that would be needed to make precise, code-specific estimates. The agency based its aggregate estimates on results of a 2013 study by HHS' Office of Inspector General of 20 high-volume and/or high-expenditure codes, which showed Medicare paying between 18 and 30 percent more than other insurers. In estimating the proposed rule's impact, CMS assumes the ultimate average reduction in payment for across all tests would be 20 percent.

For any individual test, any payment reduction from existing rates in a particular year resulting from the new payment methodology would be subject to limits specified in the statute. CMS proposes to specify a test's limit starting from the National Limitation Amount ("NLA") in 2016, rather than on 2016 payment rates, which in some localities may be below the NLA. Reductions in 2017 would be limited to 10 percent of the NLA in 2016; reductions for 2018 and 2019 would be limited to 10 percent of the prior year's rate; and reductions for 2020 through 2022 would be limited to 15 percent of the prior year's rate.

Medicaid payment rates may also be affected by the new payment system, though CMS does not present any estimate of these effects. The State Medicaid Manual states that "Medicaid reimbursement for clinical diagnostic laboratory tests may not exceed the amount that Medicare recognizes for such tests." The OIG found that Medicaid generally paid less than Medicare for most tests, but it is not clear how the Medicaid program rates compare to the amounts paid by other payers.

Will Implementation of this Proposed Rule Be Delayed?

As noted, Congress set a statutory deadline of June 30, 2015, for CMS to establish parameters for data collection under PAMA. CMS missed this deadline, releasing a proposed rule almost three months after final provisions were to have been established. The delay in establishing the data collection and reporting parameters has created an awkward schedule; for example, CMS proposes a data collection period that starts July 1, 2015, well before the proposed rule was

released and for which no notice was provided. The comment period for the proposed rule runs through Nov. 24, 2015, making it highly unlikely that CMS will release a final rule before the end of the year even though the proposed data reporting period is scheduled to start Jan. 1, 2016.

This timing is further complicated by CMS' statement that it will issue subregulatory guidance providing further clarification on numerous issues, including the form and manner for reporting applicable information; application of civil monetary penalties for applicable labs that do not report required data; and the processes for certifying data and applying to be an ADLT. For example, CMS indicates that it intends to issue guidance on reporting applicable information before the reporting period begins on Jan. 1, 2016. It is not clear how CMS could issue subregulatory guidance before CMS finalizes the data collection and payment parameters, which means that CMS could only issue its promised guidance if it can also issue a final rule in December 2015, a scenario which seems highly unlikely given the delays in releasing the proposed rule.

The scheduling constraints are likely to lead to pressures on CMS to delay both the reporting requirements and, ultimately, the rates that would be set based on the reported data.

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[1] 42 CFR § 493.2

[2] TIN is defined as "a Federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service in 26 CFR § 301.6109-1."

[3] Including fee-for-service payments under Medicare Parts A, B, C (Medicare Advantage) and D (prescription drugs).

[4] Note that although Physician Fee Schedule payments are an element of the test of what is an applicable laboratory, the PAMA provision affects only CLFS tests. Payments under the Physician Fee Schedule for diagnostic tests, such as pathology tests, are unaffected by this reform.

[5] CMS estimates that of the 68,000 unique TINs that are enrolled in Medicare and bill the CLFS, 94 percent are physician office laboratories, 3 percent are independent laboratories and the rest serve nursing homes and other niche markets.

[6] Congressional Budget Office, Cost Estimate for the Protecting Access to Medicare Act of 2014, https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/costestimate/house-introduced-protecting-access-medicare-act-2014-march-26-20140_0.pdf.