American Hospital Association

Regulatory Advisory

July 26, 2016

Final Rule on Medicare Clinical Diagnostic Laboratory Tests Payment System

AT A GLANCE

At Issue:

On June 17, the Centers for Medicare & Medicaid Services (CMS) released a long-awaited final rule that overhauls the Medicare payment system for clinical diagnostic laboratory tests (CDLTs) and for advanced diagnostic laboratory tests (ADLTs) and implements other changes required by the Protecting Access to Medicare Act of 2014 (PAMA). Consistent with the AHA's recommendation, CMS delayed the effective date of the new system for one year, until Jan. 1, 2018.

Under the final rule, "applicable laboratories," which include certain hospital community outreach laboratories, certain physician office laboratories and most independent laboratories, will be required to report private payer rate and volume data every three years. The new Medicare clinical laboratory fee schedule (CLFS) payment amounts will be based on the weighted median of the private payer rates. The vast majority of hospital-based laboratories and physician office laboratories are not expected to meet the applicable laboratories criteria and thus will be exempt from reporting. CMS estimates that the new payment system will reduce Medicare payments for laboratory tests by $390 million in fiscal year (FY) 2018 and $3.93 billion over 10 years.

The agency will post the new market-based payment amounts in early November 2017, and they will take effect Jan. 1, 2018.

Our Take:

The AHA is pleased that CMS is delaying implementation of the new payment system, per our recommendation. We believe that this should allow more time for laboratories to review the final rule and clarifying guidance; to make changes to laboratory finance information systems so as to permit correct and complete data collection and reporting; and to engage in end-to-end testing of CMS's new data reporting system. In addition, while payments for most hospital laboratory tests furnished to Medicare beneficiaries are packaged into their inpatient and outpatient prospective payment systems rates, payments for hospital community outreach testing services are made under the CLFS. Therefore, we also are pleased that CMS decided to follow the AHA's recommendation to define "applicable laboratories" at the level of the National Provider Identifier (NPI) so as to include more hospital outreach laboratories. This change should make the final rates more representative of the overall market.

What You Can Do:

- ✓ Share this advisory with your chief financial officer and other members of senior management, laboratory director, billing and coding staff, and key physician leaders.
- ✓ Review the rule to determine whether any of your community outreach laboratories will be considered an "applicable laboratory." If so, watch for more information from CMS later this month about how to report your private payer data during first quarter of calendar year 2017.

Further Questions:

For more information, please contact Roslyne Schulman, director of policy, at rschulman@aha.org.

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Final Rule on Medicare Clinical Diagnostic Laboratory Tests Payment System

BACKGROUND

On June 17, the Centers for Medicare & Medicaid Services (CMS) released a long-awaited final rule that revises the Medicare payment system for clinical diagnostic laboratory tests (CDLTs). Specifically, as required by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), the final rule requires "applicable laboratories" to report laboratory test payment rates and laboratory test volume data from private insurers every three years and bases the new Medicare clinical laboratory fee schedule (CLFS) payment amounts on a weighted median of those rates.

We are pleased that, consistent with the AHA's recommendation, CMS finalized a one-year delay, to Jan. 1, 2018, in the implementation of the new Medicare payment rates for CDLTs paid under the CLFS. Under the revised timing, the initial "data collection period" is Jan 1, 2016 through June 30, 2016 and applicable laboratories will be required to report data from this period during the "data reporting period" of Jan. 1, 2017 through March 31, 2017. CMS will use these data to calculate the weighted median payment rate for each laboratory test, which will serve as the basis for most of the revised market-based payment rates for CDLTs. The PAMA requires a six-year phase-in of these rates, under which the rate for a particular laboratory test may not be reduced by more than 10 percent from the preceding year for calendar years (CYs) 2018 through 2020, and may not be reduced by more than 15 percent for CYs 2021 through 2023. CMS will post the new Medicare payment rates for the CLFS in early November 2017, and they will be effective on Jan. 1, 2018.

The agency states that it expects the new rates to result in $390 million in payment reductions for laboratories in 2018 and $3.93 billion over 10 years.

This Regulatory Advisory summarizes the final rule's provisions. In addition, the AHA offers members a more detailed summary prepared by Health Policy Alternatives, Inc.

DEFINITION OF AN "APPLICABLE LABORATORY"

As noted above, the private payer rates that serve as the basis for the revised Medicare CLFS will be determined by aggregating data from applicable laboratories. Consistent

with the AHA's recommendation, CMS finalizes a policy that defines an applicable laboratory at the National Provider Identification (NPI) level, instead of the Internal Revenue Service (IRS) Tax Identification Number (TIN) level as had been proposed. However, CMS finalizes the requirement that "applicable information" must be reported at the TIN level. Therefore, CMS defines the "reporting entity" as a TIN-level entity that must report applicable information for all of its NPI-level components that are applicable laboratories.

In order to be considered an applicable laboratory, an entity must meet *all* of the following criteria:

- The entity is a laboratory, as defined by the Clinical Laboratory Improvement Amendments (CLIA).
- The entity bills Medicare Part B under its own NPI.
- During the "data collection period," the entity receives a majority of its Medicare revenues from payments from the CLFS and/or the physician fee schedule (PFS). CMS defines "Medicare revenues" to include all fee-for-service payments under Medicare Parts A and B, as well as all payments under Medicare Advantage and Part D plans (including beneficiary coinsurance and deductibles).
- The entity receives at least $12,500 in revenue for laboratory tests paid under the CLFS during the six-month data collection period.
    - Any entity below this "low-expenditure threshold" would not be an applicable laboratory and thus would be exempt from reporting.
    - However, the $12,500 low-revenue threshold does not apply to a laboratory that offers and furnishes advanced diagnostic laboratory tests (ADLTs), which are defined as those CDLTs offered and furnished by a single laboratory. In order to ensure that CMS receives private payer data to calculate payment rates for ADLTs, such a laboratory that falls below the low-expenditure threshold but that meets the other three criteria above will be required to report private payer data for its ADLTs to CMS. However, these laboratories will not have to report with respect to the other CDLTs they furnish.

CMS's change to define an applicable laboratory at the NPI level rather than the TIN level was made in response to concerns from AHA and other organizations that a TIN-level definition would exclude virtually all hospital laboratories, including most hospital community outreach laboratories[1], from being required to report their private payer data. This is because most hospital laboratories share the same TIN as their parent hospital, and therefore would likely fail to meet the "majority of Medicare revenues" criterion above. If hospital outreach laboratories were excluded from reporting, incomplete information would be factored into the calculations of the new CLFS payment rates, which would tend to drive down the weighted median payment rates. By contrast, defining "applicable laboratory" at the NPI level is expected to result in more hospital

[1] Hospital community outreach laboratories are hospital laboratories that furnish laboratory tests to patients who are not admitted hospital inpatients or registered outpatients of the hospital.

outreach laboratories being defined as applicable laboratories because they often have their own separate NPI.

Using these criteria, CMS expects each laboratory to independently determine whether it qualifies as an applicable laboratory for purposes of reporting. The agency notes that some laboratories may not know whether they are applicable laboratories until after the data collection period is over. A laboratory also will need to reevaluate whether it qualifies as an applicable laboratory for each data collection period: every year for ADLTs and every three years for all other CDLTs.

CMS also finalizes its proposal to prohibit voluntary reporting for entities that do not meet the definition of an applicable laboratory.

DEFINITION OF "APPLICABLE INFORMATION"

CMS requires that "applicable information" be reported during the data reporting period. Specifically, applicable laboratories will be required to report the payment rate that was paid by each private payer for each CDLT, as identified by specific Healthcare Common Procedural Coding System (HCPCS) codes, and the associated volume of each test performed during the data collection period. CMS states that the private payer rate must reflect all price concessions (e.g., discounts, rebates and coupons) and include any applicable patient cost-sharing amounts (deductibles and coinsurance). CMS defines a "private payer" as a health insurance issuer, a group health plan, a Medicare Advantage plan under Medicare Part C or a Medicaid managed care organization.

CMS also clarifies that "price concessions" only include "front-end concessions" such as volume thresholds, and do not include concessions applied by a laboratory, such as the waiver of patient coinsurance due to a patient's financial hardship. The agency also clarifies that applicable information does not have to be reported for tests paid under a capitated basis. In addition, if a private payer pays different rates for the same laboratory test during the data collection period (as in the case of a volume discount), the applicable laboratory must report each rate and its corresponding volume.

Further, CMS clarifies that if the date of the final payment for a CDLT falls within a data collection period, the payment rate will be considered to have been paid for purposes of the definition of the private payer rate. If the laboratory test claim is still under review by the private payer or is under appeal during a data collection period, the amount that has already been paid will not be considered a final payment rate and will not be used to determine a private payer rate. CMS notes that payments from secondary insurance payers will also be considered in calculating private payer rates if the final payments are made during the data collection period. In those instances where a laboratory cannot correlate a private payer amount to a specific HCPCS code, CMS notes the payment amount is not a private payer rate for purposes of applicable information.

In addition, CMS states that only private payer payment rates for CDLTs paid under the CLFS are considered for private payer payment rates. Payment rates for laboratory tests paid only under the PFS and not under the CLFS will not be private payer rates and should not be reported as applicable information.

Finally, responding to commenters' requests, CMS plans to publish a list of HCPCS codes on the CLFS website for which applicable laboratories must report private payer rates.

DEFINITION OF "ADVANCED DIAGNOSTIC LABORATORY TESTS"

The PAMA defines an "advanced diagnostic laboratory test" (ADLT) as a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner). Under the law, applicable laboratories are required to report applicable information regarding their ADLTs every year, rather than every three years as for non-ADLT laboratory tests. Further, new ADLTs will be paid using their actual list charge amount during an initial period of three quarters. CMS plans to monitor compliance to ensure that the applicable information for each ADLT is reported by a single laboratory.

Definition of Single Laboratory

In the proposed rule, CMS stated that, in order to ensure that ADLT status is granted to only the one laboratory that offers and furnishes the particular test, the laboratory could only have a single CLIA certificate. The AHA and others raised concerns that CMS's proposed definition did not reflect how laboratories operate; we advocated that, as long as the offering and furnishing laboratory does not sell the test for use by another laboratory, then the number of CLIA certificates the entity holds was irrelevant. In particular, the AHA expressed concern that the proposed requirement that a laboratory have only a single CLIA certificate would exclude many hospital-based and health system-based laboratories from being able to identify their tests as ADLTs.

CMS agreed with these concerns and revised the definition accordingly. In the final rule, a single laboratory is one that furnishes the test and may also design, offer and sell the test. In addition, the entity that owns the laboratory and the entity that is owned by the laboratory may also design, offer or sell the test. CMS believes this revision will allow a corporate entity that owns multiple laboratories to furnish a new ADLT at each laboratory site and will enable other parts of the single laboratory organization to be involved with all aspects of the ADLT, including research and development. This definition also should allow hospitals and health systems with multiple CLIA certificates to be defined as a single laboratory and thus have access to the preferential reimbursement rates for their new ADLTs.

Definition of "Successor Owner"

CMS defines a "successor owner" to mean a single laboratory that has assumed ownership of the single laboratory that designed the test or of the single laboratory that is a successor owner to the single laboratory that designed the test, through any of the following circumstances: partnership, unincorporated sole proprietorship or corporation.

Additional Requirements for ADLTs

The PAMA also requires that to qualify as an ADLT, a test must meet at least one of three additional criteria below. In the rule, CMS finalizes further definition of these criteria and states it plans to establish an application process for laboratories to request ADLT status after publication of this final rule. This publication also will include the information applicants must submit to demonstrate how the test meets the requirements of criterion A or criterion B.

Criterion 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. To qualify as a test under Criterion A, the test must:

- Be a molecular pathology analysis of multiple biomarkers of DNA, RNA or proteins. (CMS notes that an ADLT might consist of one test that analyzes multiple biomarkers or it might consist of multiple tests that each analyzes one or more biomarkers.);
- When combined with an empirically derived algorithm, yield a result that predicts the probability a specific individual patient will develop certain condition(s) or respond to a particular therapy(ies);
- Provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and
- May include other assays. (CMS indicates that an ADLT for a DNA biomarker might also include a component that analyzes proteins.)

Criterion B: The test is cleared or approved by the FDA. A laboratory test can be considered an ADLT if it is cleared or approved by the Food and Drug Administration (FDA) and meets all the other aspects of the ADLT definition (e.g., being provided by a single laboratory). A laboratory test that FDA exempted from approval or clearance and allowed the device to be legally marketed immediately without any form or premarket approval or clearance would not meet criterion B.

Criterion C: The test meets other similar criteria established by the Secretary. CMS did not set forth any additional criteria.

Definition of a "New ADLT"

CMS defined a "new ADLT" as an ADLT for which payment has not been made under the CLFS prior to Jan. 1, 2018.

DATA COLLECTION AND DATA REPORTING

Definition of "Data Collection Period" and "Data Reporting Period"

CMS finalized a six-month data collection period, from Jan. 1 through June 30. The agency also provided a six-month period of time between the data collection period and the data reporting period to allow applicable laboratories to ensure that data are complete and accurate. Therefore, following the data collection period and the subsequent six-month gap, there will be a three-month data reporting period, from Jan. 1 through March 31. Then, the following Jan. 1, CMS will implement the updated CLFS rates.

As noted, applicable laboratories must report data for CDLTs every three years. Table 1 below illustrates the final data collection and reporting periods for CLDTs. By contrast, applicable laboratories must report data for ADLTs (that are not new ADLTs) every year.

Table 1: Final Data Collection and Reporting Periods for CDLTs*

Data Collection Period	Data Reporting Period	Used for CLFS Rate Years
1/1/2016 – 6/30/2016	1/1/2017 – 3/31/2017	2018 – 2020
1/1/2019 – 6/30/2019	1/1/2020 – 3/31/2020	2021 – 2023
Continues every 3rd subsequent CY	Continues every 3rd subsequent CY	New CLFS rate every 3rd year

** Does not include ADLTs, which must be reported every year.*

Data Reporting Requirements for New ADLTs

As stated above, the PAMA requires that, for an initial period of three quarters, the payment amount for new ADLTs be based on the test's actual list charge. In the final rule, CMS revised its proposal to require that:

- The new ADLT initial period will begin only when the test has been covered under Medicare Part B and approved for ADLT status, regardless of the order in which the events take place. The date that triggers the date on which the new ADLT initial period begins will be the later of the two.
- The initial period covers three calendar quarters that begin on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or ADLT status is granted by CMS.

CMS also clarifies that the start date of a new ADLT initial period is separate and distinct from the date that corresponds to the definition of the actual list charge.

CMS also recognizes that if private payers do not cover and pay for a test until after the second quarter of the new ADLT initial period, no private payer data may be reported for the test. In these situations, CMS will use crosswalking and gapfilling methodologies to determine pricing for the new ADLT after the new ADLT initial period.

The data collection period for a new ADLT is the first six months of its initial period. Table 4 and 5 in the final rule provide an illustrative example of final data collection and reporting periods for a new ADLT.

PAYMENT METHODOLOGY

Calculation of Weighted Median

Under the final rule, the Medicare payment amount for a CDLT furnished on or after Jan. 1, 2018 is equal to the weighted median for the test based on the most recent data collection period. In the rule, CMS provides several examples of how the weighted median is calculated. As required by the PAMA, CMS notes that the payment amounts will not be subject to any adjustments, such as annual market basket, geographic, budget-neutrality or other adjustments.

Phased-in Payment Reduction

The PAMA limits the reduction in payment amounts that may result from implementation of the new payment methodology. As such, under the final rule, payments may decline by a maximum of 10 percent for each of 2018 through 2020 and 15 percent for each of 2021 through 2023. These provisions do not apply to new ADLTs or to new CDLTs. CMS will use the National Limitation Amount[2] for purposes of calculating the 10 percent reduction limit for 2018 payment amounts since that is the first year of the new fee schedule. For subsequent years subject to the phase-in, CMS will apply the applicable percentage reduction limitation to the Medicare payment rate for the preceding year.

Payment for New ADLTs

As stated above, the PAMA requires that the payment amount for a new ADLT be based on the actual list charge for the laboratory test during an initial period of three quarters. The law defines the “actual list charge” as the publicly available rate on the

[2] The National Limitation Amount (NLA) is a percentage of the median of all the state and local fee schedule amounts. The NLA is 74 percent of the median of all local Medicare payment amounts for tests with a NLA established before Jan. 1, 2001. The NLA is 100 percent of the median of the local fee schedule amounts for tests for which the NLA was first established on or after Jan. 1, 2001.

first day when the test is available for purchase by a private payer for a laboratory test.

Actual List Charge. CMS defines the "publicly available rate" as the lowest amount charged for an ADLT that is readily accessible in such forums as a company website, test registry or price listing to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

First Day a New ADLT is Available for Purchase. CMS defines the "first day a new ADLT is available for purchase" as the first day a new ADLT can be obtained by a patient, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date. A laboratory submitting a new ADLT application must attest to the actual list charge and the date the new ADLT is first performed. CMS plans to provide subregulatory guidance further describing this process before Jan. 1, 2018.

CMS notes there will be a period of time between when the test is first performed and when the test is paid the actual list charge amount. The payment amount for this time span will be based on how CMS currently pays for a test under the CLFS. That is, the Medicare Administrative Contractor (MAC) will work with a laboratory to develop a payment rate for the period of time before CMS pays at the actual list charge.

Recoupment of Payment for New ADLTs if Actual List Charge Exceeds Market Rate. The PAMA requires that if the Medicare payment amount during the new ADLT initial period (i.e., the actual list charge) is more than 130 percent of the Medicare payment amount calculated by using the weighted median methodology, the Secretary must recoup the difference. In a change from its proposed policy (in which CMS proposed to recoup the entire difference between the actual list charge and the weighted median private payer rate), in the final rule CMS clarifies that it will recoup only the difference between the Medicare payment amount based on the actual list charge and 130 percent of the weighted median private payer rate. CMS intends to issue further guidance on the operational procedures the MAC will use for recoupment purposes.

Payment for Existing ADLTs

Prior to the implementation of the new CLFS payment methodology, the PAMA requires CMS to use the methodologies for pricing, coding and coverage for ADLTs in effect before the enactment of the law (i.e., April 1, 2014), including crosswalking or gapfilling. Thus, in the final rule, CMS states that the payment amount for existing ADLTs (i.e., ADLTs for which payment has been made under the CLFS prior to Jan. 1, 2018) will be determined based on crosswalking and gapfilling for ADLTs.

Payment for Tests Where No Applicable Information is Reported

The PAMA does not address how CMS would pay for CDLTs and ADLTs when no applicable information is reported by applicable laboratories. Therefore, in these circumstances, CMS determined it will calculate the payment amount based on current regulations, i.e., using either crosswalking or gapfilling.

PENALTIES FOR NONCOMPLIANCE AND DATA CERTIFICATION

The PAMA authorizes a civil monetary penalty (CMP) if an applicable laboratory fails to comply with the reporting requirements, including a CMP of up to $10,000 per day for each failure to report or each misrepresentation or omission. In response to commenters' concerns, CMS will issue additional guidance on the assessment of CMPs, including what would constitute a failure to report, or a misrepresentation or omission in reporting. The agency notes it does not intend to assess CMPs for minor violations. CMS will work with the OIG to assess whether a CMP should be applied, and if so, the appropriate amount based on the specific circumstances. The agency also clarifies that CMPs will be assessed at the reporting entity level and not at the applicable laboratory level.

To certify data integrity, CMS requires that the president, chief executive officer or chief financial officer of a reporting entity, or an individual who has been delegated signature authority and who reports directly to such an officer, sign a certification statement and be responsible for ensuring that the applicable information reported to CMS is accurate, complete, truthful and meets all the reporting parameters.

CONFIDENTIALITY AND PUBLIC RELEASE OF LIMITED DATA

The PAMA prohibits CMS and its contractors from disclosing applicable information reported to CMS in a manner that would identify a specific payer or laboratory, prices charged or payments made to a laboratory, except to permit the Government Accountability Office, the Congressional Budget Office and the Medicare Payment Advisory Commission to review the information or, as CMS determines it is necessary, for oversight and enforcement activities.

CMS will make publically available a list of test codes and the CLFS payment rates. This information will not identify the specific payer or laboratory or, in general, the charges or payments made to a specific laboratory. Regarding new ADLTs, because the actual list charge will already be publically available, CMS does not believe publishing the CLFS rates for these tests will constitute a release of confidential information. The agency further notes that it will not publish the ADLT-furnishing laboratory's identity, but it cannot prevent the public from associating the CLFS payment information for an ADLT to the single laboratory offering and furnishing the test.

Commenters expressed concerns that the information for public review will be insufficient for analyzing and evaluating the new CLFS payment rates and suggested additional data that should be publicly available. In reply, CMS states it intends to make available to the public, before the final rates are published, a file that includes summary or aggregate-level payer rate and volume data for each test code, such as, the unweighted median private payer rate, the range of private payer rates, the total, median and mean volume, and the number of laboratories reporting. The agency is also exploring how to make available a file of the raw data. For tests it considers to be uncommon or for tests it knows are provided only by a single laboratory, CMS will not release applicable information in aggregate form or raw form. Instead, for these tests, CMS will provide the HCPCS code and CLFS rate.

CODING FOR CERTAIN CDLTS ON THE CLFS

The PAMA requires temporary codes for certain new tests, unique codes for existing tests and establishment of unique identifiers for certain tests. “New laboratory tests” are defined as FDA-approved or FDA-cleared CDLTs that are paid under the CLFS on or after Jan. 1, 2018.

Temporary Codes for Certain New Tests

CMS will use the existing HCPCS level I codes created by the CPT Editorial Panel whenever possible. The agency will use the existing HCPCS coding process to assign a temporary HCPCS level II code to new ADLTs and new CDLTs. Specifically, CMS will assign a G-code to the test that would be effective for up to two years, unless CMS decides it is appropriate to continue the use of the G-code. As has been standard practice, CMS expects to use G-codes only when CPT codes are unavailable or do not meet providers’ coding needs. Any temporary HCPCS code will be considered for replacement by a permanent CPT code when it is made available and if it satisfies CMS’s coding and payment needs.

Coding for Existing Tests

The PAMA required that no later than Jan. 1, 2016, each existing ADLT and CDLT paid under Medicare Part B have a unique HCPCS code. CMS interprets this to mean that a unique HCPCS code can describe only a single test. Since an ADLT is a single test, each existing ADLT will be assigned its own G-code. For a single existing CDLT, however, it is possible that one HCPCS code is currently used to describe more than just this single existing CDLT. In these situations, CMS will assign a G-code to existing tests that are FDA cleared and approved.

In response to comments, CMS agrees that assignment of codes should be done with transparency and multi-stakeholder input and notes that the current CLFS coding process, which is required to continue, will address the public’s needs for transparency and input into the assignment of unique codes for tests.

NEXT STEPS

The final rule was published in the June 23 Federal Register. Look for additional guidance from CMS later this month, to be posted on its CLFS web page, on how it will operationalize the requirements of the final rule including:

- how applicable information is to be reported to CMS;
- a list of HCPCS codes for which applicable laboratories must report private payer rates;
- the application process for laboratories requesting ADLT status;
- how CMS will assess CMPs, including what would constitute a failure to report or a misrepresentation or omission in reporting;
- the process for certifying the submission of applicable information to CMS; and
- CMS's operational procedures for recoupment of payments for new ADLTs that exceed the 130 percent threshold.

The new CLFS payment rates will be effective Jan. 1, 2018.

FURTHER QUESTIONS

Please contact Roslyne Schulman, director of policy, at rschulman@aha.org for more information about the final rule.