Medicare Program: Medicare Clinical Diagnostic Laboratory Tests (CDLTs) Payment System

[CMS-1621-F]

Summary of Final Rule

I. Introduction and Background

On June 17, 2016 the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule, which implements revisions to the payment methodology for clinical diagnostic laboratory tests (CDLTs) paid under the Clinical Laboratory Fee Schedule (CLFS). CMS finalizes an **implementation date of January 1, 2018** for the new Medicare payment rates for CDLTs paid under the CLFS.

Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) added section 1834A to the Social Security Act (or the Act), which required significant changes to the payment methodology for CDLTs paid under the CLFS. CMS finalizes policies that will implement payment amounts for most CDLTs by calculating the weighted median of private payor rates based on data from laboratories (known as applicable laboratories) and reported to CMS by

reporting entities during a specified collection period.

CMS finalizes policies for Medicare payment, coding and coverage requirements for CDLTs, including defining an Advanced Diagnostic Laboratory Test (ADLT). CMS finalizes the definition of an applicable laboratory to include identification of the laboratory at the National Provider Identifier (NPI) level. CMS requires the reporting of the private payor rate and volume data at the Tax Identification Number (TIN) level, so that the TIN-level entity will report for all of its NPI-level components that are applicable laboratories. The data collection period for determining 2018 CLFS payment rates will be January 1, 2016 through June 30, 2016, and the first data reporting period will be January 1, 2017 through March 31, 2017. CMS will publish preliminary CLFS rates in early September 2017, and there will be a public comment period of approximately 30 days. CMS plans to post the final 2018 CLFS rates on the CLFS website in November 2017 and the rates will be effective on January 1, 2018.

II. Provisions of the Final Rule

A. Definition of Applicable Laboratory

CMS modifies its proposed definition of applicable laboratory and finalizes that the definition of an applicable laboratory applies at the National Provider Identification (NPI) level instead of the entity that reports tax-related information to the Internal Revenue System (IRS) under a Taxpayer Identification Number (TIN). CMS finalizes the requirement to report applicable information at the TIN level and defines the reporting entity as a TIN-level entity and finalizes that the reporting entity must report applicable information for all of its NPI-level components that are applicable laboratories. Applicable laboratories will be required to report to CMS certain information about the payment rates paid by private payors for each CDLT and the corresponding volumes of such tests furnished during a specified time period.

CMS finalizes the following definitions of an applicable laboratory as an NPI entity that:

- Is a laboratory defined by the Clinical Laboratory Improvement Amendments (CLIA) (as defined in §493.2) that bills Medicare part B under its own NPI.
- Within a data collection period, must receive more than 50 percent of its Medicare revenue from the CLFS or the Physician Fee Schedule (PFS).
    - CMS finalizes a low volume threshold and excludes any laboratory that would otherwise be an applicable laboratory if it receives less than $12,500 in Medicare revenues for CLFS services paid in a 6-month data collection period.
    - The low expenditure threshold does not apply to the single laboratory that offers and furnishes an advanced diagnostic laboratory test (ADLT). If the laboratory does not meet the low expenditure threshold however, it will not be an applicable laboratory with respect to all the other CDLTs it furnishes.

B. Definition of Applicable Information

CMS finalizes its proposed definition, with modifications, that applicable information is the payment rate that was paid by each private payor for each CDLT (identified by specific HCPCS codes) and the associated volume of each test performed corresponding to each private payor rate

during the data collection period.

- Private payment rates must reflect all price concessions and include any applicable patient cost sharing amounts (deductibles and coinsurance).
    - CMS modifies the definition to clarify that the private payor rate is the final amount that was paid by a private payor for a CDLT after all private payor price concessions are applied, and does not include price concessions applied by a laboratory.
- The information does not include tests paid under a capitated basis.

As summarized below, CMS discusses the comments it received and the options it considered for defining applicable information.

Definition of private payor rate. CMS finalizes that the amount paid by a private payor for a CDLT must be the amount after all price concessions are applied and does not limit price concessions that are specified in section 1834A of the Act.[1] CMS also finalizes that the private payor rates reflect the price for a test prior to application of any deductible or coinsurance amounts owed by the patient. CMS also revises the definition of private payor rate to specify that: (1) it does not include information about denied payments and (2) it does include non-contracted amounts paid by private payors to laboratories.

In response to comments, CMS clarifies that the private payor rate information collected during the data collection period is the date of the final payment for a CDLT. If the date of the final payment for a CDLT falls within a data collection period, the payment rate would be considered to have been paid for purposes of the definition of private payor rate. If the laboratory test claim is still under review by the private payor or is under appeal during a data collection period, the amount that has already been paid would not be considered a final payment rate and would not be used to determine a private payor rate.

CMS clarifies that the amount "paid" in the definition of private payor rates means the amount the laboratory has received as final payment for the test. CMS provides the following examples:

- An initial claim that was paid in error 3 months before a data collection period and the corrected final payment was made during the data collection period would be considered a private payor rate.
- An initial claim that was paid in error 3 months before a data collection period but the corrected final payment was made after the data collection period would not be considered a private payor rate for purposes of applicable information.

CMS notes that payments from secondary insurance payors would also be considered in calculating private payor rates if the final payments were made during the data collection period. In those instances where a laboratory cannot correlate a private payor amount to a specific HCPCS code, CMS notes the payment amount is not a private payor rate for purposes of applicable information. In response to the example about manual remittances where a private payor groups test-level payments into a claims-level payment without including HCPCS-level

[1] Specific price concessions listed in section 1834A(a)(5) of the Act include discounts, rebates, and coupons and listed in section 1847A(c)(3) of the Act include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirements, chargebacks and rebates (except for Medicaid rebates under section 1927 of the Act).

payment, CMS notes that those payment amounts would not be considered applicable information.

CMS modifies the definition of private payor price concessions to clarify 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.

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

Definition of private payor. CMS finalizes its proposal to define a private payor as a health insurance issuer defined in section 2791(b)(2) of the Public Health Service (PHS) Act; a group health plan as defined in section 2791(a)(1) of the PHS Act; a Medicare Advantage plan under Medicare Part C as defined in section 1859(b)(1) of the Act; or a Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act. CMS clarifies that applicable information would include Medicare data to the extent it is collected from Medicare Advantage plans and reported to CMS.

Volume reporting requirement. CMS revises its proposal and finalizes that reporting entities must report applicable information that consists of each private payor rate for each CDLT and its corresponding volume for each of its component applicable laboratories. CMS provides an example where an applicable laboratory and private payor agree on a volume discount for a CDLT such that the first 100 tests are reimbursed at $100 and all subsequent tests beyond the first 100 are reimbursed at $90. The laboratory would report two different private payor rates for this private payor; the first would be 100 tests at $100 per test, and the second would be $90 for all tests beyond the first 100.

Reporting a specific Healthcare Common Procedure Coding System (HCPCS) code. CMS finalizes that applicable laboratories must report a specific HCPCS code for each test that specifically identifies the test being reported. CMS defines a specific HCPCS code as a code that does not include an unlisted CPT code, as established by the AMA, or a HCPCS level II miscellaneous/not otherwise classified (NOC) code, as established by the CMS HCPCS Workgroup.

C. Definition of Advanced Diagnostic Laboratory Tests (ADLTs) and New ADLTs

1. Definition of ADLT

Section 1834A(d)(5) of the Act defines an 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) and that meets one of the following criteria:

1. 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;

2. The test is cleared or approved by the FDA; or
3. The test meets other similar criteria established by the Secretary.

CMS believes the statute seeks to establish special payment status for tests that are unique and provided only by the laboratory that developed the test, or a subsequent owner of that laboratory.

As summarized below, CMS discusses the comments it received and the options it considered for finalizing the definition ADLTs.

Definition of single laboratory. CMS revises the definition of a single laboratory to mean:

1. The laboratory which furnishes the test, and that may also design, offer, and sell the test; and
2. The following entities, which may design, offer, or sell the test:
    - The entity that owns the laboratory.
    - The entity that is owned by the laboratory.

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.

Definition of original developing laboratory. CMS proposed that only one laboratory may design, market, perform and sell the test. In the proposed rule, CMS interpreted the original developing laboratory to be the same laboratory that offers and furnishes the test. CMS also considered that a laboratory offers and furnishes a test when it markets and performs the test. If more than one laboratory engages in any of these activities, the test would not meet the criteria to be an ADLT. CMS revises the proposed definition to include the statutory terms "offered and furnished" rather than "marketed and performed".

Definition of successor owner. CMS proposed to define successor owner as a laboratory that has assumed ownership of the original developing laboratory, and meets all other aspects of the ADLT definition including being a single laboratory that markets, performs, and sells the ADLT. CMS also proposed to incorporate the language in §489.18(a) describing what constitutes a change of ownership for Medicare providers to also apply to the potential changes in ownership for laboratories. As discussed in greater detail in the proposed rule, a successor owner, for purposes of an ADLT, means a single laboratory that assumed ownership of the laboratory that designed the test through any of the following circumstances: partnership, unincorporated sole proprietorship, corporation and leasing. CMS noted that under this proposal, if an original developing laboratory corporation with a test with ADLT status is merged into another laboratory corporation that has multiple CLIA certificates, the test would be a CDLT and would no longer be considered an ADLT.

CMS discusses how the revised definition of a single laboratory requires revision of the definition of successor owner. CMS finalizes that for purposes of an ADLT, a successor owner means 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:

1. Partnership - the removal, addition, or substitution of a partner, unless the partners

expressly agree otherwise, as permitted by applicable state law;
2. Unincorporated sole proprietorship – the transfer of title and property to another party; or
3. Corporation – the merger of the single laboratory corporation into another corporation, or the consolidation of two or more corporations, including the single laboratory, resulting in the creation of a new corporation. CMS also specifies that a transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

A commenter requested clarification about the role of the academic researcher who owns the intellectual property rights to a test and the academic institution who licenses the intellectual property to another entity that further develops the test for commercialization. CMS believes that by discovering the test, the academic institution partially develops the test and that the laboratory that purchased the intellectual property would not be expending its own resources on all aspects of the development of the test and therefore, could not be considered an original developing laboratory of the test. CMS also states that this laboratory could not be a successor owner if the academic institution is not the original developing laboratory or a single laboratory. As a result, CMS concludes the test would not qualify for ADLT status.

CMS finalizes the following definitions for the additional statutory requirements for defining an ADLT:

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. CMS finalizes the following requirements to qualify a test as an ADLT under Criterion A. The test:

i. Must be a molecular pathology analysis of multiple biomarkers of DNA, RNA, or proteins. (CMS notes 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.);
ii. When combined with an empirically derived algorithm yields a result that predicts the probability a specific individual patient will develop certain condition(s) or respond to a particular therapy(ies);
iii. Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. (CMS considered requiring that a new ADLT be clinically useful as well as new, but decided against this policy due to statutory limitations.); and
iv. 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. The FDA considers CDLTs to be medical devices, and CMS discusses the application process for FDA clearing and approving medical devices. CMS finalizes that a laboratory test can be considered an ADLT if it is cleared or approved by the FDA and meets all the other aspects of the ADLT definition. CMS also finalizes that 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 propose to exercise this authority. CMS states it might consider this option in future

rulemaking.

2. Definition of New ADLT

CMS proposed to define a new ADLT as an ADLT for which payment has not been made under the CLFS prior to January 1, 2017. CMS finalizes the definition of a new ADLT as an ADLT for which payment has not been made under the CLFS prior to January 1, 2018. This date change corresponds to the finalized implementation date of the private payor rate-based CLFS to January 1, 2018.

In response to comments, CMS states it plans to establish an application process for laboratories requesting ADLT status after publication of the CLFS final rule. This will also include the information applicants must submit to demonstrate how the test meets the requirements of criterion A or criterion B. In addition, in response to comments, CMS notes that although the statute does not explicitly protect ADLT application information from release under FOIA, if an applicant submits an ADLT application that includes trade secrets or certain commercial or financial information, it is possible the information could be withheld from public disclosure under FOIA exemption (b)(4). Because there is no guarantee such information will be withheld, however, laboratories will have to decide for themselves whether to apply for ADLT status and risk the possibility of public disclosure of information they do not want to be publicly disclosed. (See Section II.F in the summary.)

D. Data Collection and Data Reporting

1. Definitions

Section 1834A(a) of the Act requires applicable laboratories to report applicable information. Under section 1834A(a)(1), beginning January 1, 2016 and every 3 years thereafter (or annually for an ADLT), each applicable laboratory must report applicable information to the Secretary at a time specified by the Secretary. When considering defining the data collection and data reporting periods, CMS wanted to provide laboratories sufficient notice of their obligation to collect and report information to CMS, provide sufficient time for CMS to determine a CLFS, and publish new CLFS payment rates at least 60 days in advance of a January 1 implementation.

CMS moved the implementation date of the new CLFS to January 1, 2018. CMS revises the data reporting requirements at §414.504(a)(1) and (2) to require that:

- For CDLTs the data reporting period is a three-month period that occurs every 3 years beginning January 1, 2017.
- For ADLTs that are not new ADLTs, the data reporting period is a three-month period that occurs every year beginning January 1, 2017.

CMS finalizes a 6-month data collection period, from January 1 through June 30, for all data collection periods and a 3-month data reporting period, from January 1 through March 31 in the next year, for a data reporting period following a data collection period. Table 3, copied from the final rule, illustrates the final data collection and reporting periods.

Table 3: Final Data Collection and Reporting Periods for CDLT*

Data Collection Period	Six Month Window	Data Reporting Period	Used for CLFS Rate Years
1/1/2016 – 6/30/2016	7/1/2016 - 12/31/2016	1/1/2017 – 3/31/2017	2018 - 2020
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2020 – 3/31/2020	2021 - 2023
Continues every 3rd subsequent calendar year	Continues every 3rd subsequent calendar year	Continues every 3rd subsequent calendar year	New CLFS rate every 3rd year

* Does not include ADLTs which must be reported every year

Beginning January 1, 2019, the Secretary may establish rules to aggregate reporting which would permit applicable laboratories to combine the prices and volumes for individual tests. CMS interprets this to mean that absent rules set by the Secretary (in 2019 or later), applicable laboratories may not aggregate data. Thus, CMS states an applicable laboratory that has more than one payment rate for the same payor rate for the same test, or more than one payment rate for different payors for the same test, must report each payment rate and the volume for the test at each rate. CMS states they will not allow reporting of individual claims or report private payor names.

2. Data Reporting Requirements for New ADLTs

Section 1834A(d)(1)(A) of the Act requires the payment amount for new ADLTs to be based on actual list charges for an initial period of 3 quarters. Section 1834A(d)(2) requires applicable laboratories to report applicable information for new ADLTs for data collection not later than the last day of the 2nd quarter of the initial period. CMS proposed that the initial period should start and end on the basis of a calendar quarter, such that the first day of the initial period would be the first day of a calendar quarter and the last day of the initial period would be the last day of a calendar quarter (e.g. January 1 through March 31 is a calendar quarter).

CMS finalizes:

- 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 new ADLT initial period means a period of 3 calendar quarters that begins 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. Laboratories will no longer need to attest to the date the new ADLT is first performed because this information is no longer relevant for determining the start date of the new ADLT initial period.

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. The actual list charge is the publicly available rate on the first day the new ADLT is obtainable by a patient who is covered by private insurance, or marketed to the public as a laboratory test a patient can

receive even if the test has not yet been furnished on that date.

CMS also recognizes that if private payors do not cover and pay for a test until after the second quarter of the new ADLT initial period, no private payor 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.

Table 4, copied from the final rule, illustrates the final data collection and reporting periods for a new ADLT. In the table, CMS uses an example where a test receives a Medicare Part B coverage determination on April 6, 2018 and ADLT status is granted by CMS on May 1, 2018.

Table 4: Example of Final Data Collection and Reporting Periods for New ADLTs

Test is Covered by Medicare Part B	ADLT Status is Granted	New ADLT Initial Period (Actual List Charge)	Data Collection Period	Data Reporting Period	Data Used for CLFS (Weighted Median Private Payor Rate)
4/6/2018	5/1/2018	7/1/2018 – 3/31/2019	7/1/2018 – 12/31/2018	By 12/31/2018	4/1/2019 – 12/31/2020

Table 5, copied from the final rule, illustrates the final data collection and reporting periods for new ADLTs after the new ADLT initial period. The table uses the same example for Table 4, where the new ADLT initial period ends on March 31, 2019.

Table 5: Final Data Collection and Reporting Periods for New ADLTs (After New ADLT Initial Period)

Data Collection Period	Six Month Window	Data Reporting Period	Used for CLFS Rate Years
1/1/2019 – 6/30/2019	7/1/2019 - 12/31/2019	1/1/2020 – 3/31/2020	2021
1/1/2020 – 6/30/2020	7/1/2020 – 12/31/2020	1/1/2021 – 3/31/2021	2022
Continues every year	Continues every year	Continues every year	New CLFS rate every year

E. Data Integrity

1. Penalties for Non-Reporting

Section 1834A(a)(9)(A) of the Act authorizes the Secretary to apply a civil monetary penalty (CMP) if the Secretary determines that an applicable laboratory fails to report or made a misrepresentation or omission in reporting applicable information. The CMP may be up to $10,000 per day for each failure to report or each such misrepresentation or omission. Since the provisions of section 1834A(a)(9)(A) are similar to the provisions regarding the reporting of average sales price by the manufacturer of a drug or biological (section 1847A(d)(4)), CMS proposes to adopt a provision in §414.504(e) for implementing the provision for reporting of

applicable information from applicable laboratories that is similar to §414.806, the regulation governing drug manufacturers' reporting of Part B drug prices. CMS anticipates issuing guidance clarifying these requirements after the publication of this rule.

CMS states that it will issue additional guidance on the assessment of CMPs, including what would constitute a failure to report, or a misrepresentation or omission in spending. CMS notes it does not intend to assess CMPs for minor events. 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. CMS also clarifies in §414.504(e) that the CMPs will be assessed at the reporting entity level and not at the applicable laboratory level.

2. Data Certification

To certify data integrity, CMS proposed that the President, CEO, or CFO of an applicable laboratory or an individual who has been delegated authority to sign for, and who reports directly to the laboratory's President, CEO, or CFO, must sign a certification statement and be responsible for assuring that the applicable information reported is accurate, complete, truthful, and meets all the reporting parameters.

CMS will issue subregulatory guidance specifying the certification process for the submission of application information prior to January 1, 2018 and will take into consideration commenters' request for a certification form for applicable laboratories. CMS revises §414.504(d) to require the President, CEO, or CFO of the reporting entity or an individual who has been delegated authority to sign for, and who reports directly to, such an officer, to certify the accuracy of the data submitted for the reporting entity.

F. Confidentiality and Public Release of Limited Data

CMS or its contractors 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, except to permit the Comptroller General, the Director of CBO, and MedPAC to review the information, or as CMS determines it is necessary for oversight and enforcement activities of the HHS OIG or the Department of Justice. If CMS determines it is necessary to disclose confidential information for other circumstances, it will notify the public through the *Federal Register* or a CMS website publication. CMS does not expect this prohibition to be problematic for the Medicare Administrative Contractors (MACs) because applicable laboratories will be reporting applicable information to CMS and not the MACs.

CMS discusses why it believes these confidentiality provisions only apply to information disclosed by a laboratory under section 1834A(a), the reporting of applicable information for the purpose of establishing CLFS rates. CMS does not believe these confidentiality provisions would apply to other information that laboratories may submit to CMS, such as the information submitted in an application for ADLT status and information regarding an applicable laboratory's business structure.

CMS intends to make publically available a list of test codes and the CLFS payment rates. This information will not identify the specific payor or laboratory or, in general, the charges or payments made to a specific laboratory. Because the actual list charge for a new ADLT would

already be publically available, CMS does not believe publishing the CLFS rates for new ADLTs will harm laboratories. CMS will not publish the 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.

In response to concerns about proprietary information, CMS discusses that it does not have the authority to provide automatic protection from public disclosures under FOIA Exemption 4, if an applicant submits an ADLT application that includes a trade secret or certain commercial or financial information. An applicant submitting an ADLT application will need to mark it proprietary and confidential, and substantiate that statement by expressly claiming substantial competitive harm if the information is disclosed, and demonstrate such in a separate statement by explaining how the release would cause substantial competitive harm pursuant to the process in E.O. 12600 for evaluation by CMS.

G. Coding for Certain CDLTs on the CLFS

Section 1834A(e) of the Act requires temporary codes for certain new tests, coding for existing tests, and establishment of unique identifiers for certain tests. CMS believes that new laboratory tests refers to CDLTs (FDA approved or cleared) that are paid under the CLFS on or after January 1, 2018 and existing CDLTs refers to CDLTs (FDA approved or cleared) paid under the CLFS prior to that date.

Temporary codes for certain new tests. CMS finalizes its proposal to use the existing HCPCS coding process for assigning a temporary HCPCS level II code for new ADLTs and a new CDLT that does not already have an assigned CPT code or HCPCS level II code that meet its coding needs. Specifically, CMS would 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. CMS states that assignments of temporary codes will occur on a quarterly basis.

Coding and publication of payment rates for existing tests. Section 1834A(e)(2) requires that no later than January 1, 2016, each existing ADLT and each existing CDLT (cleared or approved by the FDA) paid for under Medicare Part B has a "unique" HCPCS and there is public reporting of the payment rate for the test. 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 would be assigned its own G code. For one existing CDLT, however, it is possible that one HCPCS code is used to describe more than one existing CDLT. In these situations, CMS finalizes its proposal to assign a G code to existing tests that are FDA-cleared or FDA-approved.

Consistent with the change in implementing the private payor rate-based CLFS to January 1, 2018, CMS will assign and publish rates for existing ADLTs and tests cleared or approved by the FDA by January 1, 2017. CMS is developing prices for ADLTs or CDLTs (cleared or approved by the FDA) that are currently priced using crosswalking or gapfilling methodology. CMS notes it is currently considering how to present the data, including how to identify when a HCPCS code uniquely describes an existing laboratory test.

Establishing unique identifiers for certain tests. For purposes of tracking and monitoring, a laboratory or manufacturer can request a unique identifier for an ADLT or a CDLT (cleared or approved by the FDA). CMS considers tracking and monitoring as activities typically associated with obtaining information included on a Medicare claim to determine factors such as utilization of a service and which beneficiary received the service. CMS finalizes its proposal that the requirements for a unique HCPCS code for ADLTs and CDLTs will also provide the unique identifier for tracking and monitoring a test.

H. Payment Methodology

1. Calculation of Weighted Median

Section 1834A(b) of the Act requires that the Medicare payment amount for a CDLT furnished on or after January 1, 2017 shall be equal to the weighted median for the test based on the most recent data collection period. CMS revises this requirement to reflect the January 1, 2018 implementation date of the revised CLFS.

CMS provides several examples of how the weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory (Tables 6 – 12 in the final rule). Medicare payment amounts under section 1834A(b)(4)(B) are not subject to any adjustments. CMS finalizes that the payment amounts under this section are not subject to any adjustments, such as geographic, budget neutrality, annual update or other adjustments.

Under current Medicare policy, certain CDLTs that are listed on the CLFS are packaged in the OPPS payment for services provided in the hospital outpatient setting on the same day as the laboratory test. CMS only pays separately for a laboratory test when it is the only service provided to a beneficiary on a given date of service or it is conducted on the same date of service as the primary service but is ordered for a different purpose and ordered by a different practitioner who ordered the other services. Also excluded from this conditional packaging policy are molecular pathology tests described by specific CPT codes. When laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid at the CLFS rate under Medicare Part B. Because these payment policies pertain to the OPPS, CMS plans to implement them in the OPPS annual rulemaking.

CMS also clarifies that the applicable information reported is not limited to private payor rates for laboratory tests furnished to Medicare beneficiaries. As defined at §414.502, private payors include health insurers, group health plans, Medicare Advantage plans, and Medicaid managed care organizations.

2. Phased-in Payment Reduction

Section 1834A(b)(3) limits the reduction in payment amounts that may result from implementation of the new payment methodology within the first 6 years (2017 through 2022). CMS finalizes the payment reduction limit to correspond to the January 1, 2018 implementation of the private payor rate based CLFS. Therefore, the applicable maximum percent reduction from the preceding year is 10 percent for years 2018 through 2020 and 15 percent for years 2021 through 2023. These provisions do not apply to new ADLTs, or new

CDLTs that are not ADLTs.

CMS finalizes the proposal to use the National Limitation Amount (NLA)[2] for purposes of applying the 10 percent reduction limit to 2017 payment amounts instead of using local fee schedule amounts. Specifically, CMS finalizes that if the weighted median calculated for a CDLT based on applicable information for 2018 would be greater than a 10 percent reduction to the 2017 NLA for the test, CMS would establish a Medicare payment amount for 2018 that is no less than 90 percent of the NLA (no more than a 10 percent reduction). For 2021 through 2023, for each year, CMS would apply the applicable percentage reduction limitation to the Medicare payment rate for the preceding year. (Table 13 in the final rule provides examples of the phase-in reduction.)

CMS plans to publish in September the preliminary payment amounts, which will reflect the full median payor rate for each CDLT for a given update for the next calendar year. Laboratories will have the opportunity to review the fully phased-in payment reduction for a given CLFS update from the preliminary CLFS payment file. The final payment file published in November will only reflect the application of the phased-in payment reduction for the next calendar year.

3. Payment for New ADLTs

Section 1834A(d)(1)(A) provides that the payment amount for a new ADLT is based on the actual list charge for the laboratory test during an initial period of 3 quarters. As discussed above (see section II.C of this summary), CMS revised the definition of a new ADLT initial period to mean a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made and ADLT status is granted by CMS. CMS finalizes that the payment rate for a new ADLT during the new ADLT initial period is equal to its actual list charge. The Act states that the actual list charge means the publicly available rate on the first day when the test is available for purchase by a private payor for a laboratory test.

- Actual list charge. CMS finalizes the proposal to define 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 finalizes the proposal that the first day a new ADLT is available for purchase is the first day a new ADLT is obtainable 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.

CMS finalizes that in its new ADLT application, the laboratory must attest to the actual list charge and the date the new ADLT is first performed. CMS plans to provide subregulatory guidance prior to January 1, 2018.

CMS notes there will be a period of time between when the test is first performed and when

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

the test is paid the actual list charge amount. CMS finalizes that a payment amount for this time span would be based on how CMS currently pays for a test under the CLFS: the MAC would work with a laboratory to develop a payment rate for the period of time before CMS pays at the actual list charge.

4. Recoupment of Payment for New ADLTs if Actual List Charge Exceeds Market Rate

Section 1834A(d)(4) requires that after the new ADLT initial period, if the Medicare payment amount during the new ADLT initial period (the actual list charge) is more than 130 percent of the Medicare payment amount calculated by using the weighted median methodology, the Secretary shall recoup the difference between the Medicare payment amount during the initial period and the Medicare payment amount based on the weighted median methodology.

CMS finalizes the following:

- New ADLTs will be paid up to 130 percent of their weighted median private payor rate.
- To determine whether the recoupment provision applies, CMS will compare the Medicare payment amount based on actual list charge paid during the new ADLT initial period and the weighted median private payor rate from applicable information reported during the new ADLT initial period.
- If the actual list charge is greater than 130 percent of the weighted median private payor rate determined during the new ADLT initial period, CMS will recoup the difference between the actual list charge and 130 percent of the weighted median private payor rate.

5. Payment for Existing ADLTs

Section 1834A(i) requires the Secretary, to use the methodologies for pricing, coding and coverage for ADLTs in effect before the enactment of PAMA (April 1, 2014), including crosswalking or gapfilling, for the period of April 1, 2014 through December 31, 2016. CMS proposed to use crosswalking and gapfilling to establish the payment rates for existing ADLTs.

In conjunction with the revised implementation date, CMS adopts corresponding changes for new ADLTs to reflect that a new ADT is an ADLT for which payment has been made under the CLFS prior to January 1, 2018. Therefore, the payment amount for existing ADLTs will be determined based on crosswalking and gapfilling for ADLTs furnished through December 2017, instead of December 31, 2016.

6. Payment for New CDLTs that are Not ADLTs

Section 1834A(c) states that payment for a CDLT, that is not an ADLT, and is assigned a new or substantially revised HCPCS code on or after the April 1, 2014 enactment of PAMA, will be determined using crosswalking or gapfilling during the initial payment period until payment rates under section 1834A(b) are established. The test must be either crosswalked to the most appropriate existing test on the CLFS or, if no existing test is comparable, paid according to a gapfilling process.

- New test. CMS currently defines "new test" in §414.502 as any CDLT for which a new or substantially revised HCPCS code is assigned on or after January 1, 2005.

CMS finalizes the proposal to replace "new test" with "new CDLT" in §414.502 and makes conforming changes throughout the regulations. CMS finalizes the definition for a new CDLT is a CDLT that is assigned a new or substantially revised HCPCS code and that does not meet the definition of an ADLT.

- Substantially revised HCPCS code. CMS defines a substantially revised HCPCS code in §414.502 as a code for which there has been a substantive change to the definition of the test or procedure to which the code applies (i.e. a new analyte or a new methodology for measuring an existing analyte-specific test). CMS finalizes this definition.

Crosswalking and Gapfilling. CMS discusses the established methodologies currently used for crosswalking and gapfilling. CMS will continue to use the current processes for CDLTs assigned new or substantially revised HCPCS codes prior to January 1, 2018.

For CDLTs that are assigned a new or substantially revised HCPCS codes on or after January 1, 2018, CMS finalizes establishing crosswalking and gapfilling processes that do not involve NLA or local fee schedule amounts. CMS will continue to use crosswalking when it determines the new CDLT is comparable to an existing test, multiple existing tests, or an existing test code. Gapfilling is required if no existing test is comparable to the new test.

Section 1834A(c)(2) specifies that the gapfilling process must take into account the following sources of information: charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payors; charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and other criteria the Secretary determines appropriate. CMS finalizes its proposal not to make any substantive changes to the factors used in gapfilling because the first four criteria are identical to the criteria currently specified in §414.508(b)(1) and CMS is not establishing other criteria for gapfilling. If CMS decides to establish additional gapfilling criteria, it will use rulemaking.

CMS finalizes its proposal for a gapfilling process for CDLTs assigned a new or substantially revised HCPCS code on or after January 1, 2018, that would be similar to the gapfilling process currently included in §414.508(b), but eliminates the references to NLA and substitutes Medicare Administrative Contractor (MAC) for carrier. In the first year, CMS finalizes that MAC-specific amounts are established for the new CDLT using the gapfilling process and in the second year, the CDLT will be paid at the median of the MAC-specific amounts.

CMS notes that the Act requires the crosswalked and gapfilled payment amounts for new CDLTs to be in effect during an initial period until payment rates under section 1834A(b) are established. CMS believes that the initial period is the period of time until applicable information is reported for a CDLT and the information can be used to establish a payment rate using the weighted median methodology.

CMS plans to continue to permit reconsideration of the basis and the amount of payment for CDLTs as it currently does under §414.509. CMS accepts reconsideration requests in written

format for 60 days after making a payment and the requestor may also request to present its reconsideration request at the next annual public clinical laboratory meeting, typically convened each July.

7. Medicare Payment for Tests Where No Applicable Information is Reported

The statute does not address how CMS must pay for CDLTs and ADLTs when an applicable laboratory reports no applicable information. CMS finalizes its proposal that for a CDLT, including ADLTs, for which it does not receive applicable information in a data reporting period, CMS will determine the payment amount based on either crosswalking or gapfilling. This policy also includes the situation where it receives no information for tests that were previously priced using gapfilling or crosswalking and for tests previously priced using the weighted median methodology.

I. Local Coverage Determination Process and Designation of MACs for CDLTs

Local Coverage Determination. CMS finalizes its proposal to maintain current LCD Process for CDLTs. Chapter 13 of the Medicare Program Integrity Manual describes the process for establishing LCDs.

Designation of MACs. Section 1834A(g)(2) of the Act provides the Secretary the discretion to designate one or more (not to exceed four) MACs to either establish LCDs for CDLTs or to both establish LCDs and process Medicare claims for payment for CDLTs. Currently, there are 12 MACs that establish LCDs and process claims for CDLTs.

CMS discusses the options and its related concerns for implementing this provision. CMS believes it has the authority to only reduce the number of MACs issuing LCDs for CDLTs, which would result in fewer contractors issuing policies for larger geographic areas.

CMS received 27 comments in response to its requests for public comment on the benefits and disadvantages of consolidating the number of MACs for developing LCDs and also whether CMS should consolidate both LCD development and claims processing. Two commenters were in favor of consolidating both LCD development and claims processing. Five commenters were in favor of only MAC LCD consolidation but did raise related concerns. Seven commenters were not in favor of having the MACs consolidate their LCDs. Regarding MAC consolidation, 3 commenters were in favor and 11 commenters were opposed to this consolidation. CMS acknowledges these comments and will give input to stakeholders as it continues to consider whether to consolidate the number of MACs developing LCDs and/or processing claims for CDLTs.

J. Other Provisions

Advisory Panel on Clinical Diagnostic Laboratory Tests. Section 1834A(f)(1) of the Act requires the Secretary to consult with an expert outside advisory panel that is to be established by the Secretary no later than July 1, 2015 and that this panel will generally provide input on the establishment of payment rates for new CDLTs. The panel must comply with the requirements of the Federal Advisory Committee Act, FACA (5 U.S.C. App.).

Notice of all meetings is required to be published in the *Federal Register*. The first meeting of the panel was held on August 26, 2015. Information regarding the panel is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

Exemption from Administrative and Judicial Review. Section 1834A(h)(1) of the Act states there will be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the establishment of payment amounts under section 1834A of the Act. CMS codifies this provision in §414.507(c).

CMS acknowledges commenters' concerns about the accuracy of the data submitted, particularly for the initial data reporting period and discusses the plan to establish a process for public review of the CLFS rates before they are finalized (see section II.F of this summary).

Sample Collection Fee. The Act increased by $2 the nominal fee for a sample collected from an individual in a SNF or a laboratory on behalf of a HHA. CMS implemented this in a Medicare Change Request effective December 1, 2014.

CMS notes that the statute does not extend the increase in the sample collection fee to sample specimens collected from patients designated as homebound.