

Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System [CMS-1621-P]

On September 25, 2015, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a notice of proposed rulemaking (NPRM) to revise the Medicare payment system for clinical diagnostic laboratory tests (CDLTs). As required by section 1834A of the Social Security Act (or the Act), added by section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), CMS proposes policies for Medicare payment, coding and coverage requirements for CDLTs. CMS proposes that applicable laboratories would be required to report private payor rate and volume data. The initial data collection period is proposed as July 1, 2015 through December 31, 2015 with the data reported to CMS by March 31, 2016. The collected information will be the basis for most of the revised payment rates for CDLTs. CMS proposes to post the new Medicare payment rates for the Clinical Laboratory Fee Schedule (CLFS) by November 1, 2016 and the rates will be effective on January 1, 2017.

Public comments are due no later than 5:00 PM on November 24, 2015.

I. Provisions of the Proposed Rule

A. Definition of Applicable Laboratory

CMS proposes that an applicable laboratory means an entity that reports tax-related information to the Internal Revenue System (IRS) under a Taxpayer Identification Number (TIN) with which all of the National Provider Identifiers (NPIs) in the entity are associated. 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.

- An applicable laboratory is either itself a laboratory (as defined in §493.2) or if it is not itself a laboratory, has at least one component that is a laboratory.
- Within a data collection period, an applicable laboratory must receive, collectively with its associated NPI entities, more than 50 percent of its Medicare revenue from the CLFS or PFS.
 - For the data collection period from July 1, 2015 through December 31, 2015, the applicable laboratory must receive collectively with its associated NPI entities, at least \$25,000 of its Medicare revenue from the CLFS.
 - For subsequent data collection periods, the applicable laboratory must receive collectively with its associated NPI entities, at least \$50,000 of its Medicare revenue from the CLFS.

As summarized below, CMS discusses the options they considered for defining an applicable laboratory and requests public comments on alternative definitions.

How to define a laboratory. CMS proposes to use the Clinical Laboratory Improvement Amendments of 1988 (CLIA) definition of laboratory at §493.2 for defining laboratory within the term applicable laboratory. A laboratory must be CLIA-certified to be paid under Medicare.

CMS also proposes that an applicable entity is an entity that itself is a laboratory under the CLIA definition or is an entity that includes a laboratory. (CMS provides an example of a health care system that is comprised of one or more hospitals, physician offices, and reference laboratories.) CMS proposes to rely on the TIN as the mechanism for defining the entity considered the applicable laboratory and discusses why they chose the TIN instead of the NPI. CMS reports that stakeholders suggested that the TIN represents the entity negotiating pricing for laboratory test. CMS also discusses the reasons they decided not to allow or require a corporate entity with multiple TINs to provide applicable information for all of its component TINs instead of each component TIN reporting separately. CMS is not sure whether this would be a practical option and whether it would affect the quality of the applicable information submitted; CMS seeks comments about this option.

What it means to receive a majority of Medicare revenues from sections 1834A, 1833(h) or 1848 of the Act. CMS proposes to define Medicare revenues to be payment received from the Medicare program, which would include fee-for-service payments under Medicare Parts A, B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period. The entity would not include in this calculation of Medicare revenues, Medicare payments made to hospital laboratories for test furnished for admitted hospital inpatients (section 1886(d)) or registered hospital outpatients (section 1833(t)). CMS also proposes that the determination of whether an entity is an applicable laboratory would be made across the entire entity, including all component NPI entities and not just NPI entities that are laboratories. CMS discusses how they believe this definition limits reporting primarily to independent laboratories and physician offices and not other entities, such as hospitals, that do not receive the majority of their revenue from the CLFS or PFS. CMS specifically proposes to prohibit any entity that does not meet the definition of applicable laboratory from reporting applicable information.

How to apply the majority of Medicare revenue criterion. CMS discusses how an entity could transition from above to below the 50 percent Medicare revenue threshold during collection periods. CMS proposes that an entity would have to report applicable information if it is above the threshold in the data collection period and acknowledges that some entities will not know whether they exceed the threshold until after the data collection period is over and these entities would need to retroactively assess their Medicare revenues during the 3-month data reporting period.

Whether to establish a low volume or low expenditure threshold to exclude an entity from the definition of an applicable laboratory. CMS proposes that any entity that would otherwise be an applicable laboratory, collectively with all of its associated NPI entities, receives less than \$50,000 in Medicare revenues for CLFS services paid under the current CLFS (section 1833(h)) and the revised CLFS (section 1834A) and billed on Form CMS 1500 (or its electronic equivalent) would not be an applicable laboratory. CMS again acknowledges that some entities will need to retroactively assess whether they exceed the low expenditure threshold during the 3-month data reporting period. CMS notes that with this threshold approximately 94 percent of physician office laboratories and 52 percent of independent laboratories would not be subject to the reporting requirements. CMS notes, however, that its definition captures most of the

laboratories with a high percentage of Medicare utilization and spending (96 percent of CLFS spending on physician office laboratories and more than 99 percent of CLFS on independent laboratories) that are subject to the reporting requirements.

CMS does not propose a low volume threshold because of concerns it could potentially exclude laboratories that perform a low volume of very expensive tests from reporting applicable information. They might reevaluate the threshold options in future rulemaking.

B. Definition of Applicable Information

CMS proposes 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.

- Private payment rate must reflect all price concessions and include any applicable patient cost sharing amounts (deductibles and coinsurance).
- The information does not include tests paid under a capitated basis.

As summarized below, CMS discusses the options they considered for defining applicable information and requests public comments on alternative definitions.

Definition of private payor rate. CMS proposes 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

Definition of private payor. CMS proposes the definition of a private payor as a health insurance issuer defined in section 2791(b)(2) of the 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.

Volume reporting requirement. CMS proposes that each applicable laboratory must report each private payor rate for each CDLT and its corresponding volume. 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. CMS proposes that the laboratory would report the 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 proposes that applicable laboratories report a specific HCPCS code for each test that specifically identifies the test being reported. CMS proposes defining 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

¹ Specific price concessions listed in section 1834A(a)(5) of the Act - discounts, rebates, and coupons - and in section 1847A(c)(3) of the Act - 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).

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;
3. The test meets other similar criteria established by the Secretary.

CMS notes that they believe 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 options they considered for defining ADLTs and request comments on these proposals. If the proposals are finalized, CMS plans to monitor compliance by confirming that applicable information for each ADLT is reported by a single laboratory and would confirm that each applicable laboratory that reports applicable information for an ADLT has a single CLIA certificate.

Definition of single laboratory. CMS proposes to ensure that ADLT status is granted to the one laboratory that offers and furnishes the particular test to require the laboratory to be a single CLIA certificate as described in §493.43(a) and (b). CMS indicates that in most instances, the laboratory's single CLIA certificate will correspond to one laboratory location or facility. Under this proposal, an entity with multiple CLIA certificates would not be a single laboratory. CMS provides an example in which a test offered by a health system consisting of multiple entities, including physician offices and independent laboratories and that has multiple CLIA certificates associated with its multiple testing locations, would not be eligible for ADLT status, even if the test met all the other ADLT criteria.²

Definition of original developing laboratory. CMS proposes that only one laboratory may design, market, perform and sell 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 notes that in certain circumstances a referring laboratory may bill for a test (section 1833(h)(5)(A)); the referring laboratory is a laboratory that receives the specimen to be tested and refers it to another laboratory, the reference laboratory, to perform the test. In this situation, because the reference laboratory performed the test, CMS notes it would be the laboratory that offered and furnished the test for purposes of the ADLT definition.

Definition of successor owner. CMS proposes to define successor owner as a laboratory that has assumed ownership of the original developing laboratory, and meets all other aspects of

² Section 493.43(b) includes the following exceptions for certain types of laboratories that may have multiple locations: (1) laboratories that are not at a fixed location; (2) not-for-profit or Federal, State, or local government laboratories that engage in limited public health testing; and (3) laboratories that are within a hospital that are located at contiguous building on the same campus and under common direction.

the ADLT definition including being a single laboratory that markets, performs, and sells the ADLT. CMS also proposes 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 that assumed ownership of the laboratory that designed the test through any of the following circumstances: partnership, unincorporated sole proprietorship, corporation and leasing. CMS notes 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. If this proposal is finalized, CMS would expect a laboratory that obtains CMS approval of ADLT status to maintain documentation on changes of ownership with transfer of rights to market, perform, and sell the ADLT to support correct claims submission and payment.

As summarized below, CMS discusses the options they considered for defining the additional criteria a test must meet to be considered an ADLT and requests comments on these proposals. CMS notes that to implement criteria A and B, they would establish guidelines for laboratories to apply for ADLT status and submit documentation to support their application through subregulatory processes prior to January 1, 2016.

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 proposes that to qualify a test under Criterion A the test:

- i. Must be a molecular pathology analysis of multiple biomarkers of DNA or RNA. (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.)

If the proposed definition for criterion A is finalized, CMS intends to have laboratories submit evidence of their empirically derived algorithms and show how their test provides new clinical diagnostic information that cannot be obtained from other tests. CMS does not consider the confidentiality provisions under section 1834A(a)(see section F in this summary) applicable to the information required under section 1834A(d). CMS does not expect to make the information in an ADLT public, but notes that the information is not explicitly protected from disclosure under the confidentiality provisions of the statute, nor from disclosure in response to a Freedom of Information Act (FOIA) request. FOIA includes an exemption for trade secrets and commercial or financial information obtained from a person that is privileged or confidential. CMS indicates that the ADLT applicant would need to substantiate this need for confidentiality by expressly claiming substantial harm if the information is disclosed and demonstrate how the release of the information would cause substantial competitive harm (delineated in E.O. 12600).

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 proposes 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 proposes that a laboratory test that FDA exempts from approval or clearance and allows the devices 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 is not proposing to exercise this authority and might consider this option in future rulemaking.

2. Definition of New ADLT

CMS proposes to define a new ADLT as an ADLT for which payment has not been made under the CLFS prior to January 1, 2017. Prior to January 1, 2017 all ADLTs would not be considered new and would be paid in accordance with current regulations at 42 CFR part 414, subpart G, including gapfilling and crosswalking methodologies. (See section H in this summary.)

D. Data Collection and Data Reporting

1. Definitions

When considering defining the data collection and date 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 proposes the data collection period should be the full calendar year, January 1 through December 31 and immediately precede the data reporting period. CMS believes a full calendar year of applicable information would provide a comprehensive set of data for calculating CLFS rates and having the data collection immediately precede the data reporting period will improve data accuracy and limit the lag time between reporting the data and the use of the information to determine CLFS payments. CMS is proposing a 6-month data collection period for 2015, July 1, 2015 through December 31, 2015; they state this time period will still provide sufficient, reliable data to determine payment rates.

CMS proposes the data reporting period is the 3-months period during which an applicable laboratory submits applicable information to CMS and immediately follows the data collection period. CMS states that a 3-month reporting period is sufficient time to make data publically available (“tentatively, first in September and then a final version in November”) before the January 1 implementation of CLFS rates. Beginning January 1, 2016, each applicable laboratory must report during the data collection period, January 1 through March 31:

- For CDLTs that are not new CDLTs, every 3 years. (See Table 1 reproduced from the proposed rule.)
- For ADLTs that are not new ADLTs, every year beginning January 1, 2016. The data collection and reporting schedule for new ADLTs is discussed below.

Table 1: Example of Data Collection and Reporting Periods for CDLT*

Data Collection Period	Data Reporting Period	Used for CLFS Rate Years
7/1/2015 - 12/31/2015	1/1/2016 – 3/31/2016	2017 - 2019
1/1/2018 – 12/31/2018	1/1/2019 – 3/31/2019	2020 - 2022
Continues every 3 rd subsequent calendar year	Continues every 3 rd subsequent calendar year	New CLFS rate every 3 rd year for 3 years

* 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 the 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 plans to require applicable laboratories to report the minimum information needed to establish CLFS payment rates. CMS plans to specify the reporting applicable information in guidance prior to the first data reporting period but expects the report to include the specific HCPCS code, the private payor rate or rates for the specific code and the volume at each private payor rate for the specific code. 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 charge for an initial period of 3 quarters. CMS proposes 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 notes this proposal is consistent with average sales price reporting for Medicare Part B drugs.

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. The information is used to determine the CLFS payment amount for a new ADLT after the new ADLT initial period. Table 2 (reproduced from the proposed rule) provides an example for the reporting for a new ADLT that is first performed by an applicable laboratory during the Q1 of 2017 on February 4, 2017. In this example, the new ADLT would follow the annual reporting schedule for existing ADLTs in calendar year 2018.

Table 2: Example of Data Collection and Reporting Periods for a New ADLT

ADLT first performed	Initial Period (three quarters)	Data Collection Period	Data Reporting Period	Used for CLFS Rate year
02/04/2017	04/01/2017 –	04/01/2017 –	By 09/30/2017	2018 - 2019

	12/31/2017	09/31/2017		
		01/01/2018 – 12/31/2018	01/01/2019 – 03/31/2019	2020

3. Cost of Data Reporting Activities

In the Regulatory Impact Analysis, CMS acknowledges there could be substantial costs associated with data reporting but they lack information to develop a cost estimate. To better understand the costs associated with this activity, CMS requests public comment on the following questions:

- How many tests on the CLFS does the applicable laboratory perform?
- For each test, how many different private payor rates does the applicable laboratory have in a given period (e.g. calendar year or other 12-month reporting period)?
- Does the applicable laboratory receive more than one rate from a private payor in a given period (e.g. calendar year or other 12-month reporting period)?
- Is the information that laboratories are required to report readily available in the applicable laboratories’ record system?
- How much time does the applicable laboratory expect will be required to assemble and report applicable information?
- What kind of personnel will the applicable laboratory be using to report the applicable information?
- What is the salary per hour for these staff?
- Is there other information not requested in the above questions that will inform the potential reporting burden being imposed by section 1834A of the Act?

E. Data Integrity

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 misrepresentation or omission. The provisions for CMPs that apply in general to the Medicare program under 42 U.S.C. 1320a-7b apply in the same manner to the laboratory applicable information data reporting process under this section. 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 (1847A(d)(4)), CMS is proposing to adopt a provision in §414.806, the regulation governing drug manufacturers’ reporting of Part B drug prices for implementing the provision for reporting of applicable information from applicable laboratories. CMS anticipates issuing guidance clarifying these requirements after the final publication of this rule.

To certify data integrity, CMS proposes 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. Prior to January 1, 2016, CMS plans to specify the process for certification in subregulatory guidance.

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 for the HHS OIG or the Department of Justice. If CMS determines it is necessary to disclose confidential information for other circumstances, they 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 they believe 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 prices 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 they cannot prevent the public from associating the CLFS payment information for an ADLT to the single laboratory offering and furnishing the test.

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 test refers to CDLTs (FDA approved or cleared) that are paid under the CLFS on or after January 1, 2017 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 proposes using the existing HCPCS coding process for assigning a temporary HCPCS level II codes for new ADLTs and a new CDLT that does not already have an assigned CPT code or HCPCS level II code. 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.

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 proposes to assign a G code to existing tests that are FDA cleared and approved.

CMS is developing prices for ADLTs or CDLTs (cleared or approved by the FDA) that are currently priced using crosswalking or gapfilling methodology and plans to publicly report their payment rates by January 1, 2016.

Establishing unique identifiers for certain tests. For purposes of tracking and monitoring, a laboratory or manufacturer can request a unique identifier for a 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 proposes 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. In the proposed rule, 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. Medicare payment amounts under section 1834A are not subject to any adjustments. CMS proposes 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 OPSS 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 test described by specific CPT codes. When laboratory test are not packaged under the OPSS and are listed on the CLFS, they are paid at the CLFS rate under Medicare Part B. Because these payment policies pertain to the OPSS, CMS plans to implement them in the OPSS annual rulemaking.

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). Specifically, the applicable percent reduction from the preceding year is 10 percent for each of 2017 through 2019 and 15 percent for each of 2020 through 2022. These provisions do not apply to new ADLTs, or new CDLTs that are not ADLTs.

CMS proposes to use the National Limitation Amount (NLA)³ for purposes of applying the 10 percent reduction limit to 2017 payment amounts instead of using local fee schedule amounts. Specifically, CMS proposes that if the weighted median calculated for a CDLT based on applicable information for 2017 would be greater than a 10 percent reduction to the 2016 NLA for the test, CMS would establish a Medicare payment amount for 2017 that is no less than 90 percent of the NLA (no more than a 10 percent reduction). For 2019 through 2022, for each year, CMS would apply the applicable percentage reduction limitation to the Medicare payment rate for the preceding year. (Table 10 in the proposed rule provides examples of the phase-in reduction.)

CMS provides an alternative option based on applying the 10 percent reduction limitation to the lower of the NLA or the local fee schedule amount; an option that retains some of the features of the current payment methodology. CMS discusses the reasons they do not propose this option including the fact they believe the statute intends a uniform national payment for the CLFS and this option would continue regional variation in the Medicare payments. CMS is also concerned this would be a significant burden to the agency.

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 D2 in this summary), CMS proposes that the initial period for a new ADLT will begin on the first day of the first full calendar quarter following the first day on which a new ADLT is performed. CMS proposes 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 proposes 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 proposes 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 proposes 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, 2017.

Based on CMS' proposal that the new ADLT initial period starts on the first day of the next calendar quarter following the first day on which a new ADLT is performed, there will be a period of time between when the test is first performed and when the test is paid the actual list

³ 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, 2016.

charge amount. CMS proposes 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.

CMS discusses how after the new ADLT initial period, the payment rate for a new ADLT is equal to the weighted median based on applicable information reported before the last day of the second quarter of the new ADLT initial period. The payment rate based on this information submitted will continue to apply to the new ADLT until the year following the next data collection period. CMS provides an example for a test that is first available in the middle of Q1 of 2017 with the new ADLT initial period beginning on the first day of Q2 of 2017. The test would be paid the actual list charge through the end of Q4 of 2017 (an initial period of 3 calendar quarters). The applicable laboratory collects applicable information in Q2 and Q3 of 2017, reports the information to CMS by the last day of Q3 of 2017 and CMS calculates a weighted median payment rate for 2018. The applicable laboratory would report applicable information for the entire 2017 year, report the information to CMS for the January through March data reporting period in 2018, and CMS would use this information for the 2019 payment rate.

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 amounts during the initial period and the Medicare payment amount based on the weighted median methodology.

CMS proposes to specify that if the difference between the Medicare payment based on actual list charge and the weighted median rate exceeds 130 percent, CMS will recoup the entire amount of the difference between the payments. CMS discusses why they believe the statute directs the Secretary to use 130 percent as the threshold for invoking recoupment but once invoked, the Secretary collects the entire amount of the difference in payment amounts. CMS also proposes to compare the Medicare payment amount based on the actual list charge paid during the new ADLT initial period and the weighted median rate calculated from the first time reporting of new ADLT applicable information. CMS intends to issue further guidance on the operational procedures the MACs would use for recoupment purposes.

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 proposes to use crosswalking and gapfilling to establish the payment rates for existing ADLTs.

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 proposes to replace “new test” with “new CDLT” in §414.502 and make conforming changes throughout the regulations. CMS’ proposed 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 proposes not to make any changes in this definition.

Crosswalking and Gapfilling. CMS discusses the established methodologies currently used for crosswalking and gapfilling. CMS notes that the annual crosswalking and gapfilling process has already occurred for codes on the 2015 CLFS and they are currently developing crosswalking and gapfilling payment rates for codes on the 2016 CLFS. CMS proposes to continue to use the current processes for CDLTs assigned new or substantially revised HCPCS codes prior to January 1, 2017.

For CDLTs that are assigned a new or substantially revised HCPCS codes on or after January 1, 2017 CMS proposes to establish crosswalking and gapfilling processes that do not involve NLA or local fee schedule amounts. CMS states they will continue to use crosswalking when they determine 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 states they are not proposing 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 they are not proposing to establish other criteria for gapfilling. If CMS decides to establish additional gapfilling criteria, they will use rulemaking.

CMS proposes to establish a gapfilling process, for CDLTs assigned a new or substantially revised HCPCS code on or after January 1, 2017, that would be similar to the gapfilling process currently included in §414.508(b), but would eliminate the references to NLA and would substitute MAC for carrier. In the first year, CMS proposes that MAC-specific amounts are established for the new CDLT using the gapfilling process and in the second year, the CDLT would 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 amount of payment for CDLTs as they currently do 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.

Public Consultation Procedures. In October 2014, CMS announced the Advisory Panel on CDLTs (79 FR 63919), and in August 2015, CMS announced membership appointments (80 FR 47491). The first meeting of the panel was held on August 26, 2015. The Act requires the Secretary to consider recommendations from the Advisory Panel when determining payment using crosswalking or gapfilling processes. CMS is proposing to specify that the public consultation process for payment for new CDLTs on or after January 1, 2017 must include the Advisory Panel's recommendations. Information regarding the Panel is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>.

CMS describes the current process to make available to the public proposed and final payment rates as well as the rationale and supporting data. For tests that are gapfilled, CMS does not typically provide explanations for the payment amounts. As statutorily required, CMS proposes to amend their regulations to explicitly indicate that for a new CDLT on or after January 1, 2017, they will provide an explanation for gapfilled payment amounts including how they took into account the Panel's recommendations.

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 no applicable information is reported by applicable laboratories. CMS proposes that for a CDLT, including ADLTs, for which they do not receive applicable information in a data reporting period, CMS will determine the payment amount based on either crosswalking or gapfilling. CMS proposes this policy would include the situation where they receive no information for tests that were previously priced using gapfilling or crosswalking and for tests previously priced using the weighted median methodology. CMS is not proposing to maintain the payment rate from the previous year because this would not reflect changes in costs or pricing for the test.

CMS notes there are several possible reasons why no applicable information would be reported including the test is not performed for a privately insured patient, the test is not performed by any applicable laboratory and laboratory failure to comply with reporting requirements. CMS estimates that in 2013 there were 17 laboratory tests with utilization completely attributed to entities that would not be defined as applicable laboratories because they do not meet the \$50,000 threshold.

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

Local Coverage Determination. CMS does not propose any changes in the 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 their related concerns for implementing this provision. CMS believes they have 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. They indicate this could be finalized within the next 2 to 4 years.

CMS is concerned that reducing the number of MACs processing claims for CDLTs would involve complex programming and operational issues including complex changes to Medicare's computer systems. CMS believes they need to conduct analyses to determine the feasibility and program desirability of consolidating the number of MACs for making coverage policies and processing claims for CDLTs. CMS raises several operational issues including the possibility that the MAC processing the laboratory claim will not be the same MAC that processes the claim of the ordering physician, a situation that may complicate the development of a full profile of the ordering physicians' practice patterns for quality and medical necessity assessments. CMS anticipates that implementation of this option would take upwards of 5 to 6 years. CMS projects the establishment of centralized LCDs for all CDLTs would probably involve an initial build-up and then a steady-state investment of between \$10 and \$15 million per year. Creating regional lab claims processors would involve higher costs that CMS does not believe would be fully offset by the reduction in the current A/B MACs operating costs.

CMS requests 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. CMS also invites other alternatives that are permissible within the scope of the legislative authority.

J. Other Provisions

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 proposes to codify this provision in §414.507(c).

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.

V. Regulatory Impact Analysis

In 2014, Medicare paid approximately \$8 billion for CDLTs. Because applicable information from applicable laboratories on the rates that are paid by private payors for CDLTs and their associated volumes for the developed of payment rates for CDLTs are not yet available, CMS states they are limited in their ability to provide estimated impacts of the proposed payment policies.

CMS does estimate an overall aggregate change in payment for services paid using the CLFS. Based on a study by the Office of Inspector General (OEI-07-11-00010, June 2013) which showed that Medicare paid between 18 and 30 percent more than other insurers for 20 high-volume and/or high-expenditure lab test, CMS established a baseline difference between Medicare CLFS payment rates and private payor rates. CMS assumed the private payor rates to be approximately 20 percent lower than the Medicare CLFS payment rates for all tests paid under the CLFS. CMS projects the Medicare program will spend \$360 million less in Part B payments for CLFS tests furnished in 2017, the 5-year impact is estimated to be \$2.94 billion less and the 10-year impact is expected to be \$5.14 billion less in program payments (see Table 11 in the rule).

CMS estimates that most entities furnishing laboratory tests paid under the CLFS are considered small businesses according to the Small Business Administration's size standards with total revenues of \$15 million or less in any one year. Using the codes for laboratories in the North American Industry Classification System, 93 percent of medical laboratories would be considered small business. CMS states that this rule will have a significant impact on a substantial number of small businesses or other small entities even with an exception for low expenditure laboratories. Based on CMS' proposal to define applicable laboratories at the TIN level, CMS estimates 68,000 unique TIN entities are enrolled as a laboratory and paid under the CLFS. Of these unique TIN entities, 94 percent are enrolled as a physician office laboratory, 3 percent are enrolled as independent laboratories while the remaining 3 percent are attributed to other types of laboratories such as those operating within a rural health clinic or skilled nursing facility.

CMS does not think the proposed rule will have a significant impact on small rural hospitals and request comments from small rural hospitals on (1) their relationships with independent clinical laboratories and (2) their potential impact of reduction in CLFS payments on their revenues and profits.

CMS determined that the CLFS provisions will not have a substantial direct effect on State and local governments, preempt State law, or otherwise have a Federalism implication. Based on 2013 claims data, CMS received only 21,627 claims for CLFS from a total of 50 states or local public health clinics (0.1 percent of total bills that billed under the CLFS). CMS notes that the proposed rule will potentially affect payments to a substantial number of laboratory test suppliers, and some effects may be significant.