DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements requirements of section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), which significantly revises the Medicare payment system for clinical diagnostic laboratory tests. This final rule also announces an implementation date of January 1, 2018 for the private payor rate-based fee schedule required by PAMA.

DATES: These regulations are effective on August 22, 2016.

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SUPPLEMENTARY INFORMATION: To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ADLT Advanced Diagnostic Laboratory Test
CCN CMS Certification Number
CDLT Clinical Diagnostic Laboratory Test
CEO Chief Executive Officer
CFR Code of Federal Regulations
CLFS Clinical Laboratory Fee Schedule
CLIA Clinical Laboratory Improvement Amendments of 1988
CMP Civil Monetary Penalty
CMS Centers for Medicare & Medicaid Services
CPT American Medical Association's Current Procedural Terminology
CR Change Request
CY Calendar Year
DNA Deoxyribonucleic Acid
FDA Food and Drug Administration
HCPCS Healthcare Common Procedure Coding System
HHA Home Health Agency
HIPAA Health Insurance Portability and Accountability Act of 1996
IRS Internal Revenue Service
LCD Local Coverage Determination
MAC Medicare Administrative Contractor
NCD National Coverage Determination
NLA National Limitation Amount
NOC Not Otherwise Classified
NPI National Provider Identifier
OPPS Hospital Outpatient Prospective Payment System
PAMA Protecting Access to Medicare Act of 2014
PFS Physician Fee Schedule
Q1 First Quarter
Q2 Second Quarter
Q3 Third Quarter
Q4 Fourth Quarter
RNA Ribonucleic Acid
SNF Skilled Nursing Facility
TIN Taxpayer Identification Number

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

Since 1984, Medicare has paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS) under section 1833(h) of the Social Security Act (the Act). Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted on April 1, 2014) added section 1834A to the Act. The statute requires extensive revisions to the Medicare payment, coding, and coverage requirements for CDLTs, as well as creates a new subcategory of CDLTs called Advanced Diagnostic Laboratory Tests (ADLTs) with separate reporting and payment requirements. In this final rule, we present our policies for implementing the requirements of section 1834A of the Act.

2. Summary of the Major Provisions

Section 1834A of the Act significantly changes how CMS will set Medicare payment rates for CDLTs that are paid for under the CLFS. In general, with certain designated exceptions, the statute requires that the payment amount for CDLTs furnished on or after January 1, 2017, be equal to the weighted median of private payor rates determined for the test, based on certain data reported by laboratories during a specified data collection period. Different reporting and payment requirements will apply to a subset of CDLTs that are determined to be ADLTs. The most significant policies adopted in this final rule include the following (more detailed descriptions follow the bulleted list):

- The implementation date for CLFS rates based on the weighted median of private payor rates.

- The definition of ''applicable laboratory''.
- The definition of ''reporting entity'' (the entity that must report applicable information).
- The definition of ''applicable information'' (the specific data that must be reported).
- The definition of ADLT.
- Data collection and data reporting schedules.
- Data integrity.
- Confidentiality and public release of limited data.
- Coding for certain CDLTs.
- The payment methodology for CDLTs.
- The local coverage determination (LCD) process and the authority to designate Medicare Administrative Contractors (MACs) for clinical diagnostic laboratory tests.

Section 1834A(b)(1)(A) of the Act requires that, for a CDLT furnished on or after January 1, 2017, the amount Medicare pays for the CDLT must be equal to the weighted median of private payor rates for the CDLT. After considering public comments recommending that we revise the implementation date of the CLFS, we have decided to move the implementation date to January 1, 2018. Thus, for a CDLT furnished on or after January 1, 2018, the amount Medicare pays will be equal to the weighted median of private payor rates for the CDLT.

Under the authority of section 1834A(a)(2) of the Act, which requires applicable laboratories to report applicable information to CMS to be used in establishing the new CLFS payment rates, we proposed to define an applicable laboratory as an entity that: (1) Reports tax-related information to the Internal Revenue Service (IRS) under a Taxpayer Identification Number (TIN) with which all of the National Provider Identifiers (NPIs) in the entity are associated; (2) is 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, as defined in § 493.2, for which the entity reports tax-related information to the IRS using its TIN; (3) in a data collection period, receives, collectively with its associated NPI entities, more than 50 percent of its Medicare revenues from the CLFS or Physician Fee Schedule (PFS); (4) for the data collection period from July 1, 2015 through December 31, 2015, receives, collectively with its associated NPI entities, at least $25,000 of its Medicare revenues from the CLFS; and (5) for all subsequent data collection periods receives, collectively with its associated NPI entities, at least $50,000 of its Medicare revenues from the CLFS.

After considering the comments we received, we are retaining some aspects of the proposed definition and revising others. In this final rule, the applicable laboratory is defined at the NPI level, rather than the TIN level, so we have removed the pieces of the definition that refer to the TIN-level entity. However, we are retaining the TIN-level entity as the ''reporting entity'' (now defined separately from the applicable laboratory), which is responsible for reporting applicable information for all of its component NPI-level entities that meet the definition of applicable laboratory. We are retaining the ''majority of Medicare revenues'' threshold, but it will be applied to the NPI-level entity, rather than the TIN-level entity. We are finalizing a low expenditure threshold, but we are revising the amount because the threshold will be applied at the NPI level as opposed to the TIN level and will reflect a 6-month data collection period instead of a full calendar year. Under our final policy, if a laboratory receives less than $12,500 of its Medicare revenues from the CLFS during the data collection period, it is excluded from the definition of applicable laboratory. For a single laboratory that offers and furnishes an ADLT, the $12,500 threshold will not apply with respect to the ADLT. This means, if the laboratory otherwise meets the definition of applicable laboratory, whether or not it meets the low expenditure threshold, it will be considered an applicable laboratory with respect to the ADLT it offers and furnishes, and must report applicable information for its ADLT. If it does not meet the threshold, it will not be considered an applicable laboratory with respect to all the other CDLTs it furnishes.

The statute requires the following applicable information to be reported for each test on the CLFS an applicable laboratory performs: (1) The payment rate that was paid by each private payor for each test during the data collection period; and (2) the volume of such tests for each such payor. We proposed to use the term ''private payor rate'' in the context of applicable information, instead of ''payment rate,'' to minimize confusion because we typically use the term payment rate to generically refer to the amount paid under the CLFS. We also proposed that the private payor rate reflect the price for a test prior to application of any deductible or coinsurance amounts owed by the patient. In this final rule we are adopting these policies as final. We proposed that only applicable laboratories may report applicable information. We are also finalizing that requirement, but rephrasing it in the regulation to conform to our final policy that reporting entities, rather than applicable laboratories, will be reporting applicable information.

Section 1834A(d)(5) of the Act specifies criteria for defining an ADLT and authorizes the Secretary to establish additional criteria. We proposed to apply the criteria specified in statute, but not any additional criteria under the statutory authority conferred upon the Secretary, and are finalizing that proposal in this final rule. In addition, in the proposed rule, we defined an ADLT, in part, to be a molecular pathology analysis of multiple biomarkers of deoxyribonucleic acid (DNA), or ribonucleic acid (RNA). However, in response to public comments, we are removing the requirement that the test be a molecular pathology analysis and permitting protein-only based tests to also qualify for ADLT status.

We proposed that the initial data collection period would be July 1, 2015, through December 31, 2015, and that all subsequent data collection periods would be a full calendar year, from January 1 through December 31. After consideration of the comments we received, and because we no longer need to implement a shortened time frame for the initial data reporting period in light of our moving the implementation date of the revised CLFS to January 1, 2018, we are adopting the policy that all data collection periods are 6 months long, from January 1 through June 30. Further, we proposed that all applicable information, except applicable information for new ADLTs, would be reported to us in a data reporting period that would begin on January 1 and end on March 31 of the year following the data collection period. We are finalizing this policy in this final rule. However, because we are finalizing that reporting entities, and not applicable laboratories, must report applicable information, we have revised the final data reporting requirements regulation accordingly.

We proposed that the applicable information for new ADLTs must be reported initially to us by the end of the second quarter of the new ADLT initial period, which we are finalizing. We also proposed that the new ADLT initial period would be a period of 3 calendar quarters that begins on the first full calendar quarter following the first day on which a new ADLT is performed. After consideration of public comments, we are revising this policy and

requiring, instead, that the data collection period for a new ADLT will begin on the first day of the first full calendar quarter following the latter of either the date a Medicare Part B coverage determination is made or ADLT status is granted by us.

The statute specifies that if, after a new ADLT initial period, the Secretary determines the payment amount that was applicable during the initial period (the test's actual list charge) was greater than 130 percent of the payment amount that is applicable after such period (based on private payor rates), the Secretary shall recoup the difference between those payment amounts for tests furnished during the initial period. We proposed to recoup the entire amount of the difference between the actual list charge and the weighted median private payer rate. After consideration of public comments, we are revising our proposed policy so that, for tests furnished during the new ADLT initial period, we will pay up to 130 percent of the weighted median private payor rate. That is, if the actual list charge is subsequently determined to be greater than 130 percent of the weighted median private payor rate, we will recoup the difference between the actual list charge and 130 percent of the weighted median private payer rate.

We proposed to apply a civil monetary penalty (CMP) to an applicable laboratory that fails to report or that makes a misrepresentation or omission in reporting applicable information. We proposed to require all data to be certified by the President, Chief Executive Officer (CEO), or Chief Financial Officer (CFO) of an applicable laboratory before it is submitted to CMS. As required by section 1834A(a)(10) of the Act, certain information disclosed by a laboratory under section 1834A(a) of the Act is confidential and may not be disclosed by the Secretary or a Medicare contractor in a form that reveals the identity of a specific payor or laboratory, or prices, charges or payments made to any such laboratory, with several exceptions. We are revising the certification and CMP policies in the final rule to require that the accuracy of the data be certified by the President, CEO, or CFO of the reporting entity, or an individual who has been delegated to sign for, and who reports directly to such an officer. Similarly, the reporting entity will be subject to CMPs for the failure to report or the misrepresentation or omission in reporting applicable information. Additionally, we are updating the CMP amount to reflect changes required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114–74, November 2, 2015).

We proposed to use G codes, which are part of the Healthcare Common Procedure Coding System (HCPCS) we use for programmatic purposes, to temporarily identify new ADLTs and new laboratory tests that are cleared or approved by the Food and Drug Administration (FDA). The temporary codes would be in effect for up to 2 years until a permanent HCPCS code is established except if the Secretary determines it is appropriate to extend the use of the temporary code. We are finalizing this policy in this final rule.

As required by section 1834A(b) of the Act, payment amounts for laboratory tests on the CLFS will be determined by calculating a weighted median of private payor rates using reported private payor rates and associated volume (number of tests). For tests that were paid on the CLFS prior to the implementation of section 1834A of the Act, PAMA requires that any reduction in payment amount be phased in over the first 6 years of payment under the new system. For new ADLTs, initial payment will be based on the actual list charge of the test for 3 calendar quarters; thereafter, the payment rate will be determined using the weighted median of private payor rates and associated volume (number of tests) reported every year. For new and existing tests for which we receive no applicable information to calculate a weighted median, we proposed that payment rates be determined by using crosswalking or gapfilling methods. These methods of determining payment were discussed in the proposed rule (80 FR 59404). We are finalizing these policies in this final rule.

Section 1834A(g)(2) of the Act authorizes the Secretary to designate one or more (not to exceed four) MACs to establish coverage policies, or establish coverage policies and process claims, for CDLTs. As noted in section II.I of the proposed rule, we requested public comment on the benefits and disadvantages of implementing this discretionary authority before making proposals on this topic. While we proposed no changes to the CDLT LCD development and implementation processes or claims processing functions in this final rule, our review of the comments received and our response to comments is contained in section II.I below.

3. Summary of Costs and Benefits

In section VI. of this final rule, we provide a regulatory impact analysis that, to the best of our ability, describes the expected impact of the policies we are adopting in this final rule. These policies, which implement section 1834A of the Act, include a process for collecting the applicable information of applicable laboratories for CDLTs. We note that, because such data are not yet available, we are limited in our ability to provide estimated impacts of the payment policies under different scenarios. However, we believe this final rule is an economically significant rule because we believe that the changes to how CLFS payment rates will be developed will overall decrease payments to entities paid under the CLFS. Accordingly, in section IV., we have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of the rulemaking.

B. Background

1. The Medicare Clinical Laboratory Fee Schedule (CLFS)

Currently, under sections 1832, 1833(a), (b), and (h), and 1861 of the Act, CDLTs furnished on or after July 1, 1984 in a physician's office, by an independent laboratory, or in limited circumstances by a hospital laboratory for its outpatients or non-patients are paid under the Medicare CLFS, with certain exceptions. Under these sections, tests are paid the lesser of (1) the billed amount, (2) the local fee schedule amount established by the Medicare contractor, or (3) a National Limitation Amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests are paid at the NLA.

Under the current system, the CLFS amounts are updated for inflation based on the percentage change in the Consumer Price Index for all urban consumers (CPI–U) and reduced by a multi-factor productivity adjustment (see section 1833(h)(2)(A) of the Act). For CY 2015, under section 1833(h)(2)(A)(iv)(II) of the Act, we also reduced the update amount by 1.75 percentage points. In the past, we have implemented other adjustments or did not apply the change in the CPI–U to the CLFS for certain years in accordance with statutory mandates. We do not otherwise have authority to update or change the payment amounts for tests on the CLFS. Generally, coinsurance and deductibles do not apply to CDLTs paid under the CLFS.

For any CDLT for which a new or substantially revised HCPCS code has been assigned on or after January 1, 2005, we determine the basis for and

amount of payment based on one of two methodologies—crosswalking and gapfilling (see section 1833(h)(8) of the Act and §§ 414.500 through 414.509). The crosswalking methodology is used when a new test is comparable in terms of test methods and resources to an existing test code, multiple existing test codes, or a portion of an existing test code on the CLFS. In such a case, we assign the new test code the local fee schedule amount and the NLA of the existing test and pay for the new test code at the lesser of the local fee schedule amount or the NLA. Gapfilling is used when no comparable test exists on the CLFS. Under gapfilling, the MACs establish local payment amounts for the new test code using the following sources of information, if available: (1) Charges for the test and routine discounts to charges; (2) resources required to perform the test; (3) payment amounts determined by other payors; and (4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. Under this gapfilling methodology, an NLA is calculated after a year of payment at the local contractor rates, based on the median of rates for the test code across all MACs. Once an NLA is established, in most cases, we can only reconsider the crosswalking or gapfilling basis and/or amount of payment for new tests for one additional year after the basis or payment is initially set. Once the reconsideration process is complete, payment cannot be further adjusted (except by a change in the CPI–U, the productivity adjustment, and any other adjustments required by statute).

In 2014, Medicare paid approximately $7 billion for CDLTs. As the CLFS has grown from approximately 400 tests to over 1,300 tests, some test methods have become outdated and some tests may no longer be priced appropriately. For example, some tests have become more automated and cheaper to perform, with little need for manual interaction by laboratory technicians, while more expensive and complex tests have been developed that bear little resemblance to the simpler tests that were performed at the inception of the CLFS.

2. Statutory Bases for Changes in Payment, Coding, and Coverage Policies for Clinical Diagnostic Laboratory Tests

Section 1834A of the Act, as added by section 216(a) of PAMA, requires extensive revisions to the Medicare payment, coding, and coverage requirements for CDLTs. In this section, we describe the major provisions of section 1834A of the Act, which we are implementing in this final rule.

Section 1834A(a)(1) of the Act requires reporting of private payor payment rates for CDLTs made to applicable laboratories to establish Medicare payment rates for tests paid under the CLFS. Applicable information must be reported to the Secretary, at a time specified by the Secretary and for a designated data collection period, for each CDLT an applicable laboratory furnishes during such period for which Medicare payment is made. Section 1834A(a)(2) of the Act defines the term ''applicable laboratory'' to mean a laboratory that receives a majority of its Medicare revenues from sections 1834A or 1833(h) of the Act (the statutory authorities under which CLFS payments are or will be made), or section 1848 of the Act (the authority under which PFS payments are made). Section 1834A(a)(2) of the Act also provides that the Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of an applicable laboratory, as the Secretary determines to be appropriate.

Section 1834A(a)(3)(A) of the Act defines the term ''applicable information'' as the payment rate that was paid by each private payor for each CDLT and the volume of such tests for each such payor for the data collection period. Under section 1834A(a)(5) of the Act, the payment rate reported by a laboratory must reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1847A(c)(3) of the Act regarding the average sales price for Part B drugs or biologicals. Section 1834A(a)(6) of the Act further specifies that, where an applicable laboratory has more than one payment rate for the same payor for the same test, or more than one payment rate for different payors for the same test, each such payment rate and the volume for the test at each such rate must be reported. The paragraph also provides that, beginning January 1, 2019, the Secretary may establish rules to aggregate reporting in situations where a laboratory has more than one payment rate for the same payor for the same test, or more than one payment rate for different payors for the same test. Under section 1834A(a)(3)(B) of the Act, information about laboratory tests for which payment is made on a capitated basis or other similar payment basis is not considered ''applicable information'' and is therefore excluded from the reporting requirements.

Section 1834A(a)(4) of the Act defines the term ''data collection period'' as a period of time, such as a previous 12-month period, specified by the Secretary. Section 1834A(a)(7) of the Act requires that an officer of each laboratory must certify the accuracy and completeness of the applicable information reported. Section 1834A(a)(8) of the Act defines the term ''private payor'' as a health insurance issuer and a group health plan (as such terms are defined in section 2791 of the Public Health Service Act), a Medicare Advantage plan under Medicare Part C, or a Medicaid managed care organization (as defined in section 1903(m) of the Act).

Section 1834A(a)(9)(A) of the Act authorizes the Secretary to apply a CMP in cases where the Secretary determines that an applicable laboratory has failed to report, or made a misrepresentation or omission in reporting, applicable information under section 1834A(a) of the Act for a CDLT. In these cases, the Secretary may apply a CMP in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission. Section 1834A(a)(9)(B) of the Act further provides that the provisions of section 1128A of the Act (other than subsections (a) and (b)) shall apply to a CMP under this paragraph in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act. Section 1128A of the Act governs CMPs that apply in general under federal health care programs. Thus, the provisions of section 1128A of the Act (specifically sections 1128A(c) through 1128A(n) of the Act) apply to a CMP under section 1834A(a)(9) of the Act in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act. That is, the existing CMP provisions apply to the laboratory data collection process under 1834A of the Act, just as the CMP provisions are applied now to other processes, such as the Medicare Part B and Medicaid drug data collection processes under sections 1847A and 1927 of the Act.

Section 1834A(a)(10) of the Act addresses the confidentiality of the information reported to the Secretary. Specifically, the paragraph provides that, notwithstanding any other provision of law, information disclosed under the data reporting requirements is confidential and shall not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identity of a specific payor or laboratory, or prices charged, or payments made to any such laboratory, except: (1) As the Secretary determines to be necessary to carry out this section; (2) to permit the Comptroller General to review the information provided; (3) to permit the Director of the Congressional Budget Office to review the information

provided; and (4) to permit the Medicare Payment Advisory Commission (MedPAC) to review the information provided. Section 1834A(a)(11) of the Act further states that a payor shall not be identified on information reported under the data reporting requirements, and that the name of an applicable laboratory shall be exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552(b)(3).

Section 1834A(a)(12) of the Act requires the Secretary to establish parameters for the data collection under section 1834A(a) of the Act through notice and comment rulemaking no later than June 30, 2015.

Section 1834A(b) of the Act establishes a new methodology for determining Medicare payment rates for CDLTs. Section 1834A(b)(1)(A) of the Act provides that, in general, the payment amount for a CDLT (except for new ADLTs and new CDLTs) furnished on or after January 1, 2017, shall be equal to the weighted median determined under section 1834A(b)(2) of the Act for the test for the most recent data collection period. Section 1834A(b)(1)(B) of the Act specifies that the payment amounts established under this methodology shall apply to a CDLT furnished by a hospital laboratory if the test is paid for separately, and not as part of a bundled payment under the hospital outpatient prospective payment system (OPPS) (section 1833(t) of the Act). Section 1834A(b)(2) of the Act provides that the Secretary shall calculate a weighted median for each test for the data collection period by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory. Section 1834A(b)(4)(A) of the Act states that the payment amounts established under this methodology for a year following a data collection period shall continue to apply until the year following the next data collection period. Moreover, section 1834A(b)(4)(B) of the Act specifies that the payment amounts established under section 1834A of the Act shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment).

Section 1834A(b)(3) of the Act requires a phase-in of any reduction in payment amounts for a CDLT for each year from 2017 through 2022. Specifically, section 1834A(b)(3)(A) of the Act requires that the payment amounts determined under the new methodology for a CDLT for each of 2017 through 2022 shall not result in a reduction in payments for that test for the year that is greater than the ''applicable percent'' of the payment amount for the test for the preceding year. Section 1834A(b)(3)(B) of the Act defines these maximum applicable percent reductions as follows: For each of 2017 through 2019, 10 percent; and for each of 2020 through 2022, 15 percent. However, section 1834A(b)(3)(C) of the Act specifies that this payment reduction limit shall not apply to a new CDLT under section 1834A(c)(1) of the Act, or to a new ADLT, as defined in section 1834A(d)(5) of the Act.

Section 1834A(b)(5) of the Act increases by $2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a sample collected from an individual in a Skilled Nursing Facility (SNF) or by a laboratory on behalf of a Home Health Agency (HHA). This provision has the effect of raising the sample collection fee from $3 to $5 when the sample is being collected from an individual in a SNF or by a laboratory on behalf of an HHA.

Section 1834A(d)(5) of the Act defines an ADLT to mean 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 meets one of the following criteria: (1) The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (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.

Section 1834A(d)(1)(A) of the Act provides that, in the case of an ADLT for which payment has not been made under the CLFS prior to April 1, 2014 (PAMA's enactment date), during an initial 3 quarters, the payment amount for the test shall be based on the actual list charge for the test. Section 1834A(d)(1)(B) of the Act defines the term ''actual list charge'' for purposes of this provision to mean the publicly available rate on the first day at which the test is available for purchase by a private payor. For the reporting requirements for such tests, under section 1834A(d)(2) of the Act, an applicable laboratory will initially be required to comply with the data reporting requirements under section 1834A(a) of the Act by the last day of the second quarter (Q2) of the initial 3 quarter period. Section 1834A(d)(3) of the Act requires that, after this initial period, the data reported under paragraph 1834A(d)(2) of the Act shall be used to establish the payment amount for an ADLT described in section 1834A(d)(1)(A) of the Act using the payment methodology for CDLTs under section 1834A(b) of the Act. This payment amount shall continue to apply until the year following the next data collection period.

Section 1834A(d)(4) of the Act addresses recoupment of payment for new ADLTs if the actual list charge exceeds the subsequently established payment amount based on market rates. Specifically, it provides that, if the Secretary determines after the initial period that the payment amount for a new ADLT based on the actual list charge was greater than 130 percent of the payment rate that is calculated using the payment methodology for CDLTs under section 1834A(b) of the Act, the Secretary shall recoup the difference for tests furnished during that initial period.

Section 1834A(c) of the Act provides for payment of new tests that are not ADLTs. Specifically, section 1834A(c)(1) of the Act provides that, in the case of a CDLT that is assigned a new or substantially revised HCPCS code on or after April 1, 2014 (PAMA's enactment date), and which is not an ADLT (as defined in section 1834A(d)(5) of the Act), during an initial period until payment rates under section 1834A(b) of the Act are established for the test, payment for the test shall be determined on the basis of crosswalking or gapfilling. Section 1834A(c)(1)(A) of the Act requires application of the crosswalking methodology described in § 414.508(a) (or any successor regulation) to the most appropriate existing test under the CLFS during that period. Section 1834A(c)(1)(B) of the Act provides that, if no existing test is comparable to the new test, the gapfilling process described in section 1834A(c)(2) of the Act shall be applied. Section 1834A(c)(2) of the Act states that this gapfilling process must take into account the following sources of information to determine gapfill amounts, if available: 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 to be appropriate. Section 1834A(c)(3) of the Act further requires that, in determining the payment amount under crosswalking or gapfilling processes, the Secretary must consider recommendations from the panel

established under section 1834A(f)(1) of the Act. In addition, section 1834A(c)(4) of the Act provides that, in the case of a new CDLT that is not an ADLT, the Secretary shall make available to the public an explanation of the payment rate for the new test, including an explanation of how the gapfilling criteria and panel recommendations described in paragraphs (2) and (3) of section 1834A(c) of the Act are applied.

Section 1834A(e) of the Act sets out coding requirements for certain new and existing tests. Specifically, section 1834A(e)(1)(A) of the Act requires the Secretary to adopt temporary HCPCS codes to identify new ADLTs (as defined in section 1834A(d)(5) of the Act) and new laboratory tests that are cleared or approved by the FDA. Section 1834A(e)(1)(B) of the Act addresses the duration of these temporary new codes. Section 1834A(e)(1)(B)(i) of the Act requires the temporary code to be effective until a permanent HCPCS code is established (but not to exceed 2 years), subject to an exception under section 1834A(e)(1)(B)(ii) of the Act that permits the Secretary to extend the temporary code or establish a permanent HCPCS code, as the Secretary determines appropriate.

Section 1834A(e)(2) of the Act addresses coding for certain existing tests. This section requires that, not later than January 1, 2016, the Secretary shall assign a unique HCPCS code and publicly report the payment rate for each existing ADLT (as defined in section 1834A(d)(5) of the Act) and each existing CDLT that is cleared or approved by the FDA for which payment is made under Medicare Part B as of April 1, 2014 (PAMA's enactment date), if such test has not already been assigned a unique HCPCS code. In addition, section 1834A(e)(3) of the Act requires the establishment of unique identifiers for certain tests. Specifically, for purposes of tracking and monitoring, if a laboratory or a manufacturer requests a unique identifier for an ADLT or a laboratory test that is cleared or approved by the FDA, the Secretary shall use a means to uniquely track such test through a mechanism such as a HCPCS code or modifier.

Section 1834A(f) of the Act addresses requirements for input from clinicians and technical experts on issues related to CDLTs. In particular, 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. This advisory panel must include an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in clinical laboratory science or health economics, or in issues related to CDLTs, which may include the development, validation, performance, and application of such tests. Under section 1834A(f)(1)(A) of the Act, this advisory panel is required to provide input on the establishment of payment rates under section 1834A of the Act for new CDLTs, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test, and the factors to be used in determining coverage and payment processes for new CDLTs. Section 1834A(f)(1)(B) of the Act states that the panel may provide recommendations to the Secretary under section 1834A of the Act. Section 1834A(f)(2) of the Act requires the panel to comply with the requirements of the Federal Advisory Committee Act (5 U.S.C. App.). A notice announcing the establishment of the Advisory Panel on CDLTs and soliciting nominations for members was published in the October 27, 2014 **Federal Register** (79 FR 63919 through 63920). The panel's first public meeting was held on August 26, 2015. Information regarding the Advisory Panel on CDLTs is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html*.

Section 1834A(f)(3) of the Act requires that the Secretary continue to convene the annual meeting described in section 1833(h)(8)(B)(iii) of the Act after the implementation of section 1834A of the Act, for purposes of receiving comments and recommendations (and data on which the recommendations are based) on the establishment of payment amounts under section 1834A of the Act.

Section 1834A(g) of the Act addresses issues related to coverage of CDLTs. Section 1834A(g)(1)(A) of the Act requires that coverage policies for CDLTs, when issued by a MAC, be issued in accordance with the LCD process, which we have outlined in Chapter 13 of the Medicare Program Integrity Manual.

In addition, section 1834A(g)(1)(A) of the Act states that the processes governing the appeal and review of CDLT-related LCDs shall continue to follow the general rules for LCD review established by CMS in regulations at 42 CFR part 426.

Section 1834A(g)(1)(B) of the Act states that the CDLT-related LCD provisions referenced in section 1834A(g) of the Act do not apply to the national coverage determination (NCD) process (as defined in section 1869(f)(1)(B) of the Act). Section 1834A(g)(1)(C) of the Act specifies that the provisions pertaining to the LCD process for CDLTs, including appeals of LCDs, shall apply to coverage policies issued on or after January 1, 2015.

In addition, section 1834A(g)(2) of the Act authorizes the Secretary to designate one or more (not to exceed four) MACs to either establish LCDs for CDLTs, or to both establish CDLT-related LCDs and process Medicare claims for payment for CDLTs, as determined appropriate by the Secretary.

Section 1834A(h)(1) of the Act states that there shall be no administrative or judicial review under sections 1869, 1878, or otherwise, of the establishment of payment amounts under section 1834A of the Act. Section 1834A(h)(2) of the Act provides that the Paperwork Reduction Act in chapter 35 of title 44 of the U.S.C. shall not apply to information collected under section 1834A of the Act.

Section 1834A(i) of the Act states that during the period beginning on the date of enactment of section 1834A of the Act (April 1, 2014) and ending on December 31, 2016, the Secretary shall use the methodologies for pricing, coding, and coverage for ADLTs in effect on the day before this period. This may include crosswalking or gapfilling methods.

II. Provisions of the Proposed Regulations and Responses to Public Comments

We received approximately 1,300 public comments from individuals, health care providers, corporations, government agencies, trade associations, and major laboratory organizations. The following are the proposed provisions, a summary of the public comments we received related to each proposal, and our responses to the comments.

A. Definition of Applicable Laboratory

Section 1834A(a)(1) of the Act requires an ''applicable laboratory'' to report applicable information for a data collection period for each CDLT the laboratory furnishes during the period for which payment is made under Medicare Part B. The statute requires reporting to begin January 1, 2016, and to take place every 3 years thereafter for CDLTs, and every year thereafter for ADLTs. Section 1834A(a)(2) of the Act defines an applicable laboratory as a laboratory that receives a majority of its Medicare revenues from section 1834A and section 1833(h) (the statutory authorities for the CLFS) or section 1848 (the statutory authority for the PFS) of the Act. Section 1834A(a)(2) of the Act

also allows the Secretary to establish a low volume or low expenditure threshold for excluding a laboratory from the definition of an applicable laboratory, as the Secretary determines appropriate.

In establishing a regulatory definition for ''applicable laboratory,'' we considered the following issues: (1) How to define ''laboratory;'' (2) what it means to receive a majority of Medicare revenues from sections 1834A, 1833(h), or 1848 of the Act; (3) how to apply the majority of Medicare revenues criterion; and (4) whether to establish a low volume or low expenditure threshold to exclude an entity from the definition of applicable laboratory.

First, we considered what a laboratory is, and we incorporated our understanding of that term in our proposed definition of applicable laboratory. The CLFS applies to a wide variety of laboratories (for example, national chains, physician offices, hospital laboratories, etc.), and we believed it was important that we define laboratory broadly enough to encompass every laboratory type that is subject to the CLFS.

We searched for existing statutory definitions of ''laboratory'' that could be appropriate to use for the revised CLFS. However, section 1834A of the Act does not define laboratory, nor is it defined elsewhere in the Medicare statute. So we looked to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a definition. CLIA applies to all laboratories performing testing on human specimens for a health purpose, including but not limited to those seeking payment under the Medicare and Medicaid programs (§ 493.1). To be paid under Medicare, a laboratory must be CLIA-certified (§ 410.32(d) and part 493). Therefore, we believed it was appropriate to use the CLIA definition of laboratory at § 493.2 for our purposes of defining laboratory within the term applicable laboratory. We did not consider alternative definitions of laboratory as we were not able to identify alternative definitions that would be appropriate for consideration under section 1834A of the Act.

CLIA defines a laboratory as a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both), or only serving as a mailing service and not performing testing, are not considered laboratories, which we believed was also appropriate for our purposes. The services of those facilities that only collect or prepare specimens or serve as a mailing service are not paid on the CLFS. We proposed to incorporate the CLIA regulatory definition of laboratory into our proposed definition of applicable laboratory in § 414.502 by referring to the CLIA definition at § 493.2 to indicate what we mean by laboratory.

We indicated in the proposed rule that, under the revised payment system for CDLTs, an applicable laboratory is the entity that reports applicable information to CMS. However, not all entities that meet the CLIA regulatory definition of laboratory would be applicable laboratories under our proposal. Here, we discuss which entities we believe should be required to report applicable information.

Laboratory business models vary throughout the industry. For example, some laboratories are large national networks with multiple laboratories under one parent entity. Some laboratories are single, independent laboratories that operate individually. Some entities, such as hospitals or large practices, include laboratories as well as other types of providers and suppliers. We proposed that an applicable laboratory is an entity that itself is a laboratory under the CLIA definition or is an entity that includes a laboratory (for example, a health care system that is comprised of one or more hospitals, physician offices, and reference laboratories). Within our proposed definition of applicable laboratory, we indicated that if the entity is not itself a laboratory, it has at least one component that is a laboratory, as defined in § 493.2.

We proposed that, whether an applicable laboratory is itself a laboratory or is an entity that has at least one component that is a laboratory, the applicable laboratory would be required to report applicable information. Entities that enroll in Medicare must provide a TIN, which we use to identify the entity of record that is authorized to receive Medicare payments. The TIN-level entity is the entity that reports tax-related information to the Internal Revenue Service (IRS). When an entity reports to the IRS, the entity and its components are all associated with that entity's TIN. We would rely on the TIN as the mechanism for defining the entity we consider to be the applicable laboratory. Therefore, we proposed that the TIN-level entity is the applicable laboratory.

We explained that each component of the TIN-level entity that is a covered health care provider under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations will have an NPI. The NPI is the HIPAA standard unique health identifier for health care providers adopted by HHS (§ 162.406). Health care providers, which include laboratories that transmit any health information in electronic form in connection with a HIPAA transaction for which the Secretary has adopted a standard, are required to obtain NPIs and use them according to the NPI regulations at 45 CFR part 162, subpart D. When the TIN-level entity reports tax-related information to the IRS, it does so for itself and on behalf of its component NPI-level entities. We indicated this in the proposed definition of applicable laboratory by stating that the applicable laboratory is the entity that reports tax-related information to the IRS under a TIN with which all of the NPIs in the entity are associated. We also proposed to define TIN and NPI in § 414.502 by referring to definitions already in the Code of Federal Regulations.

We considered defining an applicable laboratory at the NPI level instead of the TIN level. Some stakeholders indicated that, because they bill Medicare by NPI and not TIN, the NPI would be the most appropriate level for reporting applicable information to Medicare. However, because the purpose of the revised Medicare payment system is to base CLFS payment amounts on private payor rates for CDLTs, which we expect would be negotiated at the level of the entity's TIN, as described previously, and not by individual laboratory locations at the NPI level, we proposed that an applicable laboratory be defined at the level of a TIN. Further, numerous stakeholders suggested that the TIN represents the entity negotiating pricing and is the entity in the best position to compile and report applicable information across its multiple NPIs when there are multiple NPIs associated with a TIN. We stated in the proposed rule that we believed defining an applicable laboratory by TIN rather than by NPI would result in the same applicable information being reported, and would require reporting by fewer entities, and therefore, would be less burdensome to applicable laboratories. In addition, we stated that we did not believe reporting at the TIN level would affect or diminish the quality of the applicable information reported. To the

extent the information is accurately reported, reporting at a higher organizational level should produce exactly the same applicable information as reporting at a lower level. Therefore, we proposed to define applicable laboratory by TIN rather than by NPI.

We also considered whether to separate the mechanics of reporting from the definition of an applicable laboratory. For example, we considered allowing or requiring a corporate entity with multiple TINs to provide applicable information for all of its TINs along with a list of component TINs. Under this approach, the corporate entity would report each distinct private payor rate and the associated volume across all component TINs instead of each component TIN reporting separately. Thus, if the same rate was paid by a private payor in two or more of the corporate entity's component TINs, the entity would report the private payor rate once and the associated sum of the volume of that test across the component TINs. We stated in the proposed rule that we believed this approach may be operationally less burdensome than submitting separate data files by TIN or NPI. We also stated that we did not believe such reporting would affect the quality of the applicable information because we should still arrive at the same weighted median for each test. We opted not to propose this option, however, because we are not familiar enough with the corporate governance of laboratories to know whether this even higher level of reporting would be a desirable or practical option for the industry and whether it would affect the quality of the applicable information we would receive.

Next, we considered what it means for an applicable laboratory to receive a majority of Medicare revenues from sections 1834A, 1833(h), or 1848 of the Act. We proposed to define Medicare revenues to be payments received from the Medicare program, which would include fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage payments under Medicare Part C, and 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. We applied the standard meaning of ''majority,'' which is more than 50 percent. Under our proposal, in deciding whether an entity meets the majority criterion of the applicable laboratory definition, it would examine its Medicare revenues from sections 1834A, 1833(h), and 1848 of the Act to determine if those revenues (including any beneficiary deductible and coinsurance amounts), whether from only one or a combination of all three sources, constitute more than 50 percent of its total revenues under the Medicare program for the data collection period. In determining its Medicare revenues from sections 1834A, 1833(h), and 1848 of the Act, the entity would not include Medicare payments made to hospital laboratories for tests furnished for admitted hospital inpatients or registered hospital outpatients because payments for these patient care services are made under the statutory authorities of section 1886(d) of the Act (for the Hospital Inpatient Prospective Payment System (IPPS)) and section 1833(t) of the Act (for the OPPS), respectively, not sections 1834A, 1833(h), or 1848 of the Act. In other words, an entity would need to determine whether its Medicare revenues from laboratory services billed on Form CMS 1500 (or its electronic equivalent) and paid under the current CLFS (section 1833(h) of the Act), the CLFS under PAMA (section 1834A of the Act), and the PFS (section 1848 of the Act) constitute more than 50 percent of its total Medicare revenues for the data collection period.

Moreover, for the entity evaluating whether it is an applicable laboratory, the ''majority of Medicare revenues'' determination would be based on the collective amount of its Medicare revenues received during the data collection period, whether the entity is a laboratory under § 493.2 or is a larger entity that has at least one component that is a laboratory. We proposed 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 those NPI entities that are laboratories. We proposed to specify in the definition of applicable laboratory that an applicable laboratory is an entity that receives, collectively with its associated NPI entities, more than 50 percent of its Medicare revenues from one or a combination of the following sources: 42 CFR part 414, subpart G; and 42 CFR part 414, subpart B. The regulatory citations we proposed to include in the definition are the regulatory payment provisions that correspond to the three statutory provisions named in section 1834A(a)(2), that is, sections 1834A, 1833(h), and 1848 of the Act.

We noted that section 1834A(a)(1) of the Act only mandates reporting from entities meeting the definition of an applicable laboratory. We stated in the proposed rule that we believed the purpose of only mandating applicable laboratories to report applicable information is to ensure we use only their applicable information to determine payment rates under the CLFS beginning January 1, 2017, and not information from entities that do not meet the definition of applicable laboratory. We believed that, by specifying that only applicable laboratories must report applicable information, and specifying in the definition of applicable laboratory that an applicable laboratory must receive the majority of its Medicare revenues from PFS or CLFS services, the statute limits reporting primarily to independent laboratories and physician offices (other than those that meet the low expenditure or low volume threshold, if established by the Secretary) and does not include other entities (such as hospitals or other health care providers) that do not receive the majority of their revenues from PFS or CLFS services. For this reason, we proposed to prohibit any entity that does not meet the definition of applicable laboratory from reporting applicable information to CMS, which we reflect in paragraph (g) of the proposed data reporting requirements in § 414.504.

We stated that we expected most entities that fall above or below the ''majority of Medicare revenues'' threshold will tend to maintain that status through the course of their business. However, it is conceivable that an entity could move from above to below the threshold, or vice-versa, through the course of its business so that, for example, for services furnished in one data collection period, an entity might be over the ''majority of Medicare revenues'' threshold, but below the threshold in the next data collection period. We proposed that an entity that otherwise meets the criteria for being an applicable laboratory, would have to report applicable information if it is above the threshold in the given data collection period. Some entities will not know whether they exceed the threshold until after the data collection period is over; in that case, they would have to retroactively assess their Medicare revenues during the 3-month data reporting period. However, we expected that most entities will know whether they exceed the threshold long before the end of the data collection period. Under our proposal, an entity would need to reevaluate its status as to whether it falls above or below the ''majority of Medicare revenues'' threshold for every data collection period, that is, every year for ADLTs and every 3 years for all other CDLTs. We proposed this requirement would be

reflected in the definition of applicable laboratory in § 414.502.

Finally, we proposed to establish a low expenditure threshold for excluding an entity from the definition of applicable laboratory, as permitted under section 1834A(a)(2) of the Act, and we included that threshold in our proposed definition of applicable laboratory in § 414.502. We stated in the proposed rule that we believed it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a test, and minimizing the reporting burden for entities that receive a relatively small amount of revenues under the CLFS. We expected many of the entities that meet the low expenditure threshold will be physician offices and will have relatively low revenues for laboratory tests paid under the CLFS.

For purposes of determining the low expenditure threshold, we reviewed Medicare payment amounts for physician office laboratories and independent laboratories from CY 2013 Medicare CLFS claims data. In the proposed rule, we noted that, although the statute uses the term ''expenditure,'' in this discussion, we would use the term ''revenues'' because, from the perspective of applicable laboratories, payments received from Medicare are revenues rather than expenditures, whereas expenditures refer to those same revenues, but from the perspective of Medicare (that is, to Medicare, those payments are expenditures). In our analysis, we assessed the number of billing physician office laboratories and independent laboratories that would otherwise qualify as applicable laboratories, but would be excluded from the definition under various revenue thresholds. We did not include in our analysis hospitals whose Medicare revenues are generally under section 1833(t) of the Act for outpatient services and section 1886(d) of the Act for inpatient services, as these entities are unlikely to meet the proposed definition of applicable laboratory.

We found that, with a $50,000 revenue threshold, the exclusion of data from physician office laboratories and independent laboratories with total CLFS revenues below that threshold, did not materially affect the quality and sufficiency of the data we needed to set rates. In other words, we were able to substantially reduce the number of entities that would be required to report (94 percent of physician office laboratories and 52 percent of independent laboratories) while retaining a high percentage of Medicare utilization (96 percent of CLFS spending on physician office laboratories and more than 99 percent of CLFS spending on independent laboratories) from applicable laboratories that would be required to report. In the proposed rule, we indicated that we did not believe excluding certain entities with CLFS revenues below a $50,000 threshold would have a significant impact on the weighted median private payor rates.

With this threshold, using Medicare utilization data, we estimated that only 17 tests would have utilization completely attributed to laboratories not reporting because they fell below a $50,000 threshold. We understand that Medicare claims data are not representative of the volume of laboratory tests furnished in the industry as a whole; however, we believed this was the best information available to us for the purpose of determining a low expenditure threshold for the proposed rule. Therefore, we proposed that any entity that would otherwise be an applicable laboratory, but that receives less than $50,000 in Medicare revenues under section 1834A and section 1833(h) of the Act for laboratory tests furnished during a data collection period, would not be an applicable laboratory for the subsequent data reporting period. In determining whether its Medicare revenues from sections 1834A and 1833(h) are at least $50,000, the entity would not include Medicare payments made to hospital laboratories for tests furnished for hospital inpatients or hospital outpatients. In other words, an entity would need to determine whether its Medicare revenues from laboratory tests billed on Form CMS 1500 (or its electronic equivalent) and paid under the current CLFS (under section 1833(h) of the Act) and the revised CLFS (under section 1834A of the Act) are at least $50,000. We proposed that if an applicable laboratory receives, collectively with its associated NPI entities (which would include all types of NPI entities, not just laboratories), less than $50,000 in Medicare revenues for CLFS services paid on Form CMS 1500 (or its electronic equivalent), the entity would not be an applicable laboratory.

As discussed in the proposed rule (80 FR 59399), we proposed an initial data collection period of July 1, 2015, through December 31, 2015 (all subsequent data collection periods would be a full calendar year). In conjunction with the shortened data collection period for 2015, we proposed to specify that, during the data collection period of July 1, 2015, through December 31, 2015, to be an applicable laboratory, an entity must have received at least $25,000 of its Medicare revenues from the CLFS, as set forth in 42 CFR part 414, subpart G. During each subsequent data collection period, to be an applicable laboratory, an entity would have to receive at least $50,000 of its Medicare revenues from the CLFS, as set forth in 42 CFR part 414, subpart G.

We stated that, as with the ''majority of Medicare revenues'' threshold, some entities will not know whether they meet the low expenditure threshold, that is, if they receive at least $50,000 in Medicare CLFS revenues in a data collection period (or $25,000 during the initial data collection period) until after the data collection period is over; in that case, they would have to retroactively assess their total Medicare CLFS revenues during the subsequent 3-month data reporting period. However, for many entities, it will be clear whether they exceed the low expenditure threshold even before the end of the data collection period. Under our proposal, an entity would need to reevaluate its status as to the $50,000 low expenditure threshold during each data collection period, that is, every year for ADLTs and every three years for all other CDLTs. We proposed to codify the low expenditure threshold requirement as part of the definition of applicable laboratory in § 414.502.

We did not propose a low volume threshold. As indicated in the proposed rule, once we obtain applicable information under the new payment system, we may decide to reevaluate the threshold options in future years and propose different or revised policies, as necessary, which we would do through notice and comment rulemaking.

In summary, we proposed to define an applicable laboratory to mean an entity that reports tax-related information to the IRS under a TIN with which all of the NPIs in the entity are associated. An applicable laboratory would either itself be a laboratory, as defined in § 493.2, or, if it is not itself a laboratory, have at least one component that is. In a data collection period, an applicable laboratory must have received, collectively with its associated NPI entities, more than 50 percent of its Medicare revenues from either the CLFS or PFS. For the data collection period from July 1, 2015 through December 31, 2015, for purposes of calculating CY 2017 payment rates, the applicable laboratory must have received, collectively with its associated NPI entities, at least $25,000 of its Medicare revenues from the CLFS, and for all subsequent data collection periods, at least $50,000 of its Medicare revenues from the CLFS. We proposed to codify

this definition of applicable laboratory in § 414.502.

A discussion of the comments we received on our proposed definition of applicable laboratory and our responses to those comments are provided below.

Comment: While some commenters agreed with our proposal to designate applicable laboratories according to an entity's TIN, many objected. Those that objected asserted overwhelmingly that defining an applicable laboratory using the TIN would exclude hospital laboratories from the definition of applicable laboratory because, in calculating the applicable laboratory's majority of Medicare revenues amount, which looks at the percentage of Medicare revenues from the PFS and CLFS across the entire TIN-level entity, virtually all hospital laboratories would not be considered an applicable laboratory. Commenters stated that hospital laboratories compete with independent laboratories and therefore must be able to report private payor rates in order for CMS to more accurately reflect the private payor market for laboratory services under the revised CLFS.

Many commenters expressed particular concern about the exclusion of hospital outreach laboratories under our proposed definition of applicable laboratory. Commenters asserted that hospital outreach laboratories, which do not provide laboratory services to hospital patients, are direct competitors of the broader independent laboratory market, and excluding them from the definition of applicable laboratory would result in incomplete and inappropriate applicable information, which would skew the CLFS payment rates. Commenters maintained that, if the majority of all laboratories are not permitted to report private payor rate information, CMS's policy would ignore the intent of Congress to include all sectors of the laboratory market in establishing the new Medicare rates for clinical diagnostic laboratory services. Commenters stressed that, in order to set accurate market-based rates, CMS needs to ensure reporting by a broad scope of the laboratory market.

Response: We believe the statute supports the effective exclusion of hospital laboratories by virtue of the majority of Medicare revenues criterion in section 1834A(a)(2) of the Act. Section 1834A(a)(2) provides that, to qualify as an applicable laboratory, the majority of the laboratory's Medicare revenues are derived from the CLFS or the PFS (the laboratory's total Medicare revenues being the denominator, and revenues from the CLFS and PFS being the numerator in the ratio). Under our proposal, an entity would determine its total Medicare payments received from the Medicare program, including fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage payments under Medicare Part C, and 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. An entity would then calculate its revenues from sections 1834A, 1833(h), and 1848 of the Act to determine if those revenues (including any beneficiary deductible and coinsurance amounts), whether from only one or a combination of all three sources, constituted more than 50 percent of its total revenues under the Medicare program for the data collection period. Because payments for IPPS and OPPS services are made under the statutory authorities of sections 1886(d) and 1833(t) of the Act, respectively, not sections 1834A, 1833(h), or 1848, they would not be included in the numerator of the ratio. Most hospital laboratories will not meet the majority of revenues threshold because their revenues under the IPPS and OPPS alone will likely far exceed the revenues they receive under the CLFS and PFS. Therefore, we believe the statute supports limiting reporting primarily to independent laboratories and physician offices.

We agree with commenters, however, that hospital outreach laboratories should be accounted for in the new CLFS payment rates. Hospital outreach laboratories are laboratories that furnish laboratory tests for patients that are not admitted hospital inpatients or registered outpatients of the hospital. They are distinguishable from hospital laboratories in that they are enrolled in Medicare separately from the hospital of which they are a part, that is, they can be enrolled as independent laboratories that do not serve hospital patients. We believe it is important not to prevent private payor rates from being reported for hospital outreach laboratories so that we may have a broader representation of the national laboratory market to use in setting CLFS payment amounts. We address below how we are revising our definition of applicable laboratory to account for hospital outreach laboratories.

Comment: Many commenters recommended that the CLIA certificate, rather than the TIN, be used to identify the organizational entity that would be considered an applicable laboratory. Under this approach, each entity that has a CLIA certificate would be an applicable laboratory. They explained that because the denominator of the majority of Medicare revenues ratio would only include PFS and CLFS revenues, the denominator would more or less equal the numerator of the formula and would therefore ensure that an entity exceeded the threshold criterion. Another commenter, that requested applicable laboratory be defined by the CLIA certificate, suggested the following approach for calculating the majority of Medicare revenues amount. If CMS used the CLIA certificate to define applicable laboratory, then a hospital laboratory's Medicare revenues from PFS and CLFS would be compared to the hospital laboratory's total Medicare revenues, including Medicare laboratory revenue obtained from inpatient and outpatient hospital laboratory sources, as opposed to the hospital's total Medicare revenue. Commenters believed this approach would qualify hospital laboratories as applicable laboratories, which would allow for the reporting of market-based payment rates, as they believe Congress intended.

Response: We considered the commenters' suggestions to define applicable laboratory by CLIA certificate. As we indicated above, we do not believe it is appropriate to establish an applicable laboratory definition to purposely qualify hospital laboratories as applicable laboratories. We do, however, distinguish hospital outreach laboratories from hospital laboratories (as discussed above), and believe we should define applicable laboratory so that hospital outreach laboratories would not, in effect, be excluded. In addition to the potential for a CLIA certificate-based definition of applicable laboratory to be overly inclusive by including all hospital laboratories, not just hospital outreach laboratories, we do not agree with commenters as to how the majority of Medicare revenues criterion would be applied with this option.

If we used the commenters' suggested approach to define an applicable laboratory by CLIA certificate, the majority of Medicare revenues criterion would be applied only to the revenues received by the laboratory (as identified by its CLIA certificate) and not to the entire organization, if the laboratory is part of an organization that provides laboratory and other services. For example, in the case of a hospital laboratory, the numerator of the majority of Medicare revenues ratio would be the revenues the hospital received for the CLFS and PFS services furnished in its laboratory, and the denominator would be all of the revenues the hospital received for the

laboratory services provided to hospital inpatients and outpatients. However, as laboratory services provided to hospital inpatients and outpatients are typically not separately paid, it is unclear to us how revenues for these services would be determined for the denominator of the ratio. Laboratory services provided to Medicare hospital inpatients are not paid on a fee-for-service basis, but rather, are bundled into Medicare's IPPS. In addition, beginning January 1, 2014, 3 months prior to the enactment of PAMA, CMS began packaging nearly all laboratory services performed for registered hospital outpatients into the OPPS. Thus, most hospital outpatient laboratory services are also not paid on a fee-for-service basis.

The CLIA certificate is used to certify that a laboratory meets applicable health and safety regulations in order to furnish laboratory services. CLIA certificates are not associated with Medicare billing so, unlike for example, the NPI, with which revenues for specific services can easily be identified, the CLIA certificate cannot be used to identify revenues for specific services. The TIN, like the NPI, can be used to determine revenues and costs for tax purposes where revenues for CLFS or PFS services can be distinguished from other Medicare revenues. We do not see how a hospital would determine whether its laboratories would meet the majority of Medicare revenues threshold (and the low expenditure threshold) using the CLIA certificate as the basis for defining an applicable laboratory. In addition, given the difficulties many hospitals would have in determining whether their laboratories are applicable laboratories, we also believe hospitals may object to using the CLIA certificate as commenters advocate.

Comment: One commenter, concerned that our proposed definition of applicable laboratory would exclude hospital outreach services, suggested an alternative approach so that hospital outreach laboratories could potentially be included. Under the commenter's approach, the hospital would determine the proportion of its overall Medicare revenues attributable to the hospital laboratory and whether the hospital laboratory derives a majority of its Medicare revenues from the CLFS and PFS. The commenter suggested, in order to determine the total Medicare revenues attributed to the hospital laboratory, a hospital could establish an adjustment factor based on its payment-to-charges ratio. The adjustment factor would be applied to the hospital's total Medicare revenues received at the TIN level to determine the portion of Medicare revenues attributed to the hospital laboratory. The hospital would then add the revenues paid under the CLFS and PFS for non-hospital patients and for non-bundled outpatient laboratory services, the sum of which would be the estimated total Medicare revenues attributed to the hospital laboratory (the denominator). Under the commenter's approach, the majority of Medicare revenues threshold would be applied to the hospital's laboratory rather than to the entire hospital. If the hospital laboratory revenues from the PFS and CLFS exceeded 50 percent of the hospital laboratory's total Medicare revenue, it would meet the majority of Medicare revenues threshold.

Response: As discussed below, we are defining applicable laboratory at the NPI level, which we believe addresses the industry's concern that hospital outreach laboratories not be excluded from the definition of applicable laboratory. Given this change in how we are defining applicable laboratory, we do not believe it is necessary to establish a hospital adjustment factor to enable hospital outreach laboratories to be applicable laboratories. Hospital outreach laboratories will be able to be included as applicable laboratories under the final policy we are adopting.

Comment: Many commenters recommended that the definition of applicable laboratory be established at the NPI level rather than the TIN level because doing so would increase the number of hospital laboratories that would qualify as applicable laboratories. They stated that the NPI is included on claims submitted by laboratories and can be easily used to determine whether the laboratory meets the majority of Medicare revenues criterion for being an applicable laboratory. Other commenters were opposed to defining applicable laboratory in terms of the NPI because they believed not all laboratories are identified separately by an NPI. They stated that very few hospital laboratories have laboratory-specific NPIs, even those with robust laboratory outreach programs, and laboratory services claims are generally submitted under the hospital's NPI. However, commenters that favored using the NPI suggested hospital laboratories that function as outreach laboratories may enroll in Medicare as independent laboratories, under a separate NPI, in which case they could meet the definition of applicable laboratory. They believed this approach would ensure that hospital outreach laboratories, in particular, would meet the definition of applicable laboratory.

Response: We considered the commenters' suggestions to define applicable laboratory by the NPI rather than the TIN. Under this approach, the criteria for being an applicable laboratory would be applied by each laboratory with an NPI. So, for example, in determining whether the majority of Medicare revenues criterion is met, the NPI-level entity would compare its revenues under the CLFS and PFS to its own total Medicare revenues which, in the case of a hospital outreach laboratory, could presumably be comprised of only CLFS and PFS revenues. A primary benefit to this approach is that it would allow a hospital outreach laboratory, either currently enrolled in Medicare as an independent laboratory (in which case it would already have its own NPI) or that obtains a unique NPI (separate from the hospital) and bills for its hospital outreach services (that is, services furnished to patients other than inpatients or outpatients of the hospital) using its unique NPI, to meet the definition of an applicable laboratory. As we discussed above, an advantage of enabling private payor rates to be reported for hospital outreach laboratories is that there will be a broader representation of the national laboratory market on which to base CLFS payment amounts. Hospital laboratories that are not outreach laboratories, on the other hand, would be unlikely to get their own NPI and bill Medicare for laboratory services because the laboratory services they furnish are typically primarily paid for as part of bundled payments made to the hospital under the IPPS and OPPS.

As discussed previously in this section, given that the purpose of the revised Medicare payment system is to base CLFS payment amounts on private payor rates, which we expect would be negotiated at the level of the entity's TIN and not by individual laboratory locations at the NPI level, we proposed that an applicable laboratory be defined at the TIN level instead of the NPI level. In addition, while we were developing the proposed rule, many stakeholders suggested that the TIN-level entity is the one that negotiates pricing and is in the best position to collect private payor rates and report applicable information for its multiple NPI-level entities when there are multiple NPI-level entities associated with a TIN. Defining applicable laboratory in terms of the NPI rather than the TIN, however, is consistent with our view that the statute supports limiting reporting to primarily independent laboratories and physician office laboratories. That is, the statute defines an applicable laboratory as a laboratory that receives a majority of its

Medicare revenues from the PFS and the CLFS, which predominantly includes independent laboratories and physician office laboratories.

However, we proposed to define applicable laboratory in terms of the TIN rather than the NPI, in part, to minimize the reporting burden on the laboratory industry. We have concerns about the administrative burden the reporting requirement may place on applicable laboratories by defining applicable laboratories in terms of the NPI. We believe that defining applicable laboratory by the NPI, while retaining the reporting requirement at the TIN level, will result in the same applicable information being reported to CMS, but will require reporting by fewer entities, which will be less burdensome to the laboratory industry. Therefore, although we are changing the definition of applicable laboratory to apply at the NPI level, we are retaining the requirement to report applicable information at the TIN level. Under this approach, the TIN-level entity will still be required to report applicable information to CMS for all of its component NPI-level entities that meet the definition of applicable laboratory. We are calling these TIN-level entities ''reporting entities'' and are establishing a definition in § 414.502, which we discuss in more detail in this section.

We are not prescribing how a reporting entity should coordinate with its component applicable laboratories to collect and prepare applicable information for submission. The TIN-level entity and any NPI-level entities that are applicable laboratories will establish their own approach for ensuring that the TIN-level entity reports applicable information for laboratory services provided by the NPI-level entities. However, in deciding how to collect applicable information and prepare it for reporting, entities may want to consider that, in this final rule, data integrity will be certified for the reporting entity under § 414.504(d) (as discussed in section II.E.2), and the reporting entity will be the entity to which civil penalties may be applied under § 414.504(e) (as discussed in section II.E.1). We will provide the details for how applicable information is to be reported to CMS through subregulatory guidance.

In light of the changes described above, we are modifying our proposed definition of applicable laboratory at § 414.502. Specifically, we are removing the first two requirements from the proposed definition that pertained to the TIN-level entity. Because all NPI-level entities that qualify as applicable laboratories will be laboratories, we are specifying that an applicable laboratory is a laboratory as defined in § 493.2 that bills Medicare part B under its own NPI. Because we are defining applicable laboratory in terms of the NPI rather than the TIN, we are specifying in the definition of applicable laboratory that the majority of Medicare revenues threshold is to be applied by the NPI-level entity, that is, the applicable laboratory, rather than by the TIN-level entity collectively with all its associated NPIs.

In addition, as discussed later in this section, we are revising the dollar amount for the low expenditure threshold from $50,000 to $12,500, which is also reflected in the revised definition of applicable laboratory. And, because the initial data collection period will no longer be shorter than the subsequent data collection periods (as discussed further below), the definition of applicable laboratory will no longer reflect a different low expenditure threshold for the initial data collection period. Additionally, as discussed later in this section, we are also not applying the low expenditure threshold to the single laboratory that offers and furnishes an ADLT with respect to that laboratory's ADLTs, so we are adding a provision to that effect.

Comment: Many commenters suggested that CMS should separate the reporting of applicable information from the definition of applicable laboratory. Commenters recommended that, even if applicable laboratories are defined at the NPI level, the data reporting requirement should remain with the TIN-level entity. Some commenters who recommended that we identify applicable laboratories by CLIA certificate also suggested a bifurcated approach to defining applicable laboratory and reporting applicable information whereby applicable laboratories would be identified by CLIA certificates, and the businesses that own the CLIA certificate-level entities would report applicable information in one report by either their TIN or NPI.

While many commenters supported our proposal for reporting applicable information at the TIN level, some commenters also suggested that we be flexible in allowing applicable information to be reported at the TIN level, the NPI level, or the CLIA certificate level.

Response: We considered commenters' suggestions to continue to require the TIN-level entity to report applicable information even if we decided to define the applicable laboratory at a level other than the TIN. As discussed above, we are defining applicable laboratory at the NPI level, so under the approach suggested by commenters, while the NPI-level entity would be the applicable laboratory, the TIN-level entity would report the NPI-level entity's applicable information. Depending on the entity's organizational structure, sometimes the NPI-level entity will be a component of the TIN-level entity, but sometimes it will itself also be the TIN-level entity, for example, when a laboratory, as defined in § 493.2, is not owned by and does not own other entities. Therefore, sometimes the applicable laboratory will also be the reporting entity.

We believe that reporting at the TIN level will require reporting from fewer entities overall and will therefore be less burdensome to all types of applicable laboratories—that is independent laboratories, physician office laboratories, and hospital outreach laboratories—than would requiring applicable laboratories to report. We indicated in the proposed rule (80 FR 59392) that we do not believe reporting at the TIN level would affect or diminish the quality of the applicable information reported, and we noted that reporting at the higher level should produce exactly the same applicable information as reporting at the lower level. We still believe that to be the case even though we are no longer defining applicable laboratory to be the TIN-level entity.

We do not agree with the comments suggesting we allow applicable information to be reported at the TIN level, the NPI level, or the CLIA certificate level. We believe such flexibility could result in confusion among applicable laboratories as to which entity will be reporting for a given data reporting period. For example, under the commenters' suggested approach, for an organization in which a TIN-level entity is comprised of multiple NPI-level entities that meet the definition of applicable laboratory, the organization might designate an NPI-level entity to report applicable information for the initial data reporting period, but might decide to shift the reporting responsibility to the another NPI-level entity or the TIN-level entity for the next. We are concerned about the possibility of confusion as to which entity has reporting responsibilities, which could result in duplicative or no reporting.

For these reasons, we are finalizing our proposal that applicable information must be reported by the TIN-level entity. We believe section 1834A(a)(1) of the Act supports this final policy. A fundamental requirement of the statute is that the applicable information of

applicable laboratories must be reported. While we are operationalizing section 1834A(a)(1) of the Act by designating an entity other than the applicable laboratory to report, we are adhering to the essential requirement of the statute. Accordingly, we are adding the definition of reporting entity to § 414.502 to state that the reporting entity is the entity that reports tax-related information to the Internal Revenue Service using its TIN for its components that are applicable laboratories. We are also revising the data reporting requirements in § 414.504(a) to require a reporting entity to report applicable information for each CDLT furnished by its component applicable laboratories.

Comment: Many commenters requested that laboratories not meeting the definition of applicable laboratory still be permitted to voluntarily report private payor rates. The commenters urged us to consider allowing an option whereby laboratories that do not meet the definition of applicable laboratory may still report applicable information if they wish to do so. They contend that this option would make the new rates under the revised CLFS, which are based on the median of private payor rates, more representative of the total laboratory market. One commenter stated that our proposal to prohibit any entity that does not meet the definition of applicable laboratory from reporting applicable information does not appear in the statute and is not inferable from the statute. Another commenter suggested that an entity, that is not itself an applicable laboratory but that has the ability to report applicable information more efficiently and effectively than the applicable laboratories it owns or controls, should be permitted to do so.

Response: The statute is clear about the particular information that is to be reported and on which we must base the new CLFS payment rates. Only applicable information of applicable laboratories is to be reported, and section 1834A(a)(3) of the Act indicates that applicable information is private payor rate information. The statute imposes parameters on the collection and reporting of private payor rate information, and section 1834A(b) of the Act specifies that the payment amounts for CDLTs are to be based on the median of the private payor rate information. As such, we believe the statute supports our policy to prohibit information other than statutorily specified private payor rate information of applicable laboratories from being reported and used to set CLFS payment amounts under the revised CLFS. Therefore, we do not agree with the commenters' recommendation to allow voluntary reporting. At § 414.504(g), we proposed that an entity that does not meet the definition of an applicable laboratory may not report applicable information. We are finalizing that requirement, but rephrasing it as follows to conform to our final policy that reporting entities are distinct from applicable laboratories: Applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory.

Comment: Two commenters stated that our proposed low expenditure threshold would have a negative effect on the pricing of point of care tests provided by physician office laboratories (POLs). Point of care tests will be priced by crosswalking or gapfilling methodologies if they are only furnished by POLs that are below the low expenditure threshold, or they will be priced using only private payor rate information furnished by independent laboratories (which only provide a minority of these tests), and those rates could be lower than the rates paid by private payors to POLs.

The commenters suggested we establish a POL-dependent test CLFS revenue threshold to address POLs performing tests that are performed primarily or exclusively in the POL setting. Specifically, they proposed that CMS identify test codes for which POLs perform the test 50 percent or more of the time (by procedure volume). The commenters suggested that CMS could identify any POL that would not otherwise meet the definition of applicable laboratory (because the laboratory is below the low expenditure threshold) but that performs more than a significant threshold percentage, as determined by CMS, of the POL-dependent test. The commenters stated that CMS would contact such POLs and require that they report applicable information solely for those POL-dependent tests, so POL laboratories would not report applicable information for any test codes other than for POL-dependent tests that meet the criteria suggested. Furthermore, the POL could decline to report if it did not perform the test during the data collection period. Additionally, the commenter suggested for the purpose of reporting POL-dependent tests, a data collection period should be limited to no more than 3 months (or some other appropriate timeframe that balances the benefit of enhanced data collection with avoiding unnecessary reporting burden on physician offices). Moreover, the commenter requested that POL test-dependent laboratories not be liable for the civil monetary penalties outlined in the statute for good-faith errors in reporting. Under the suggested approach, for each POL-dependent test code, CMS would combine the data reported by applicable laboratories together with the data from POLs meeting the POL-dependent test CLFS revenue threshold for that test to determine the weighted median private payor amount.

Response: We considered establishing a POL-dependent test CLFS revenue threshold based on criteria we set that could potentially achieve the goal of increasing reporting for POL tests. Under this approach, we could identify the POL-dependent test codes that a POL must report and establish a low volume or low expenditure threshold above which a POL would be required to report private payor data. Although we acknowledge that, without a POL-dependent test CLFS revenue threshold, our payment methodology could result in the use of crosswalking or gapfilling instead of private payor data to establish rates for tests furnished exclusively in the POL setting, our data show that the number of laboratory tests that are exclusively or primarily performed by POLs is not significant. Furthermore, as discussed in the proposed rule (80 FR 59394), we estimated there are only 17 tests on the CLFS for which we would receive no data under our proposed definition of applicable laboratory with the low expenditure threshold. Therefore, we have decided not to pursue the commenters' suggested approach. In addition, we note that the statute does not support exempting some laboratories from the application of CMPs, as commenters suggest. We also note that we cannot provide information on the effect on revenue for POLs without knowing the resulting crosswalked or gapfilled amount determined for these tests and what would have been paid using the weighted median private payor rate. Although we have decided not to establish a POL-dependent test CLFS revenue threshold in this final rule, we may revisit the issue in a future rule as we gain more programmatic experience under the new CLFS and continue to refine payment for laboratory tests under the CLFS.

Comment: One commenter disagreed with our analysis of the amount of data we expect to receive under the proposed low expenditure threshold. The commenter stated that it appears the low expenditure threshold would result in all laboratories above the low expenditure threshold being required to report, despite some payment rate information, such as payments made on a capitated or other similar payment

basis, being statutorily excluded from the definition of applicable information. The commenter contended that, without knowledge of contractual arrangements between laboratories and private payors, CMS's estimation of the amount of applicable information it will be collecting, even after applying the low expenditure threshold, is undoubtedly overstated. The commenter stated that the quality and sufficiency of data needed to set rates is unknown and therefore requested a significant decrease in the low expenditure threshold in order to ensure the volume of private payor rate data collected is sufficient.

Response: We are not decreasing the low expenditure threshold in response to this comment; however, we are decreasing it commensurate with the shorter data collection period we are finalizing in this rule, as discussed below. We do not agree with the commenter's reasons for significantly decreasing the low expenditure threshold. First, a significant decrease in the low expenditure threshold could potentially result in a significant increase in the reporting burden on the laboratory industry without a proportionate improvement in the quality and accuracy of the data reported. Second, we continue to believe our analysis, which suggests we will receive a very high percentage of market data with the low expenditure threshold we proposed, is reliable. While we acknowledge that our analysis based on Medicare CLFS data is not a perfect proxy for private payor rate data, it reflects the type of private payor rates that will be reported as applicable information by applicable laboratories. For instance, by excluding capitated payments and other similar payments, the statute predominately defines applicable information as fee-for-service (FFS) private payor rates. Therefore, as discussed later in this section, to determine the low expenditure threshold, we reviewed Medicare FFS payment amounts from CY 2013 Medicare CLFS claims data. Based on our analysis, we found that setting a $12,500 threshold and using data collected at the NPI level for a 6-month data collection period, we could retain a high percentage of Medicare FFS utilization under the CLFS from the applicable information reported for applicable laboratories. Further, because CLFS payments will be based on the weighted median of private payor rates, additional reporting may not be likely to change payment amounts, irrespective of how many additional smaller laboratories are required to report, if, as our analysis suggests, the largest laboratories dominate the market and therefore most significantly affect the payment rates. Once we obtain applicable information under the new payment system, we may decide to reevaluate the low expenditure threshold in future years and propose a different threshold amount through notice and comment rulemaking.

Comment: One commenter requested that we not apply the low expenditure threshold to laboratories that offer and furnish new ADLTs. The commenter stated that, by definition, a new ADLT is furnished by a single laboratory. Thus, if the laboratory that furnishes the new ADLT has under $50,000 in Medicare CLFS revenues, there will be no private payor data for the laboratory to report, even though the statute specifically includes provisions for reporting private payor data by the end of the second quarter of the new ADLT initial period and on annual basis thereafter. If no private payor data is reported, payment amounts will be determined under gapfilling or crosswalking methodologies which, the commenter contends, negates the intention of the statute, which is for new ADLTs to be priced based on reported private payor rates. Therefore, the commenter believes the low expenditure threshold should not apply to those applicable laboratories that offer and furnish new ADLTs. However, the commenter requested that, if CMS does apply a low expenditure threshold to laboratories that offer and furnish new ADLTs, it should do so consistent with the proposed low expenditure threshold for the initial data collection period, that is, $25,000 in Medicare revenues under the CLFS, in order to correspond to the shorter data collection period for ADLTs during the new ADLT initial period.

Response: The statute requires the applicable information of applicable laboratories to be reported and defines an applicable laboratory as one that derives the majority of its Medicare revenues from the PFS and CLFS. The statute also provides the Secretary with the authority to establish a low volume or low expenditure threshold as the Secretary determines appropriate. As such, the application of the majority of Medicare revenues threshold criterion is mandatory for defining an applicable laboratory, while the application of the low expenditure threshold criterion is discretionary for defining an applicable laboratory.

As noted by the commenter, we would not receive private payor rate data from laboratories offering and furnishing an ADLT that have CLFS revenues below the low expenditure threshold, which means we would need to use crosswalking or gapfilling methodologies to develop a payment amount for the test after the new ADLT initial period. Given that the statute contemplates private payor rates being reported for ADLTs by the end of the second quarter of the new ADLT initial period, we do not believe it is appropriate to apply a discretionary threshold if it excludes the single laboratory that offers and furnishes an ADLT from the definition of an applicable laboratory. If the single laboratory offering and furnishing an ADLT is excluded, we would not receive any private payor rate data for the test. For this reason, we agree with the commenter that the low expenditure threshold should not be applied to single laboratories offering and furnishing ADLTs. Therefore, we are finalizing a policy to exclude laboratories offering and furnishing ADLTs from the low-expenditure threshold, but only with respect to the ADLTs offered and furnished by the single laboratory. If the single laboratory offering and furnishing an ADLT otherwise meets the definition of applicable laboratory, but does not meet the low expenditure threshold, that is, even if it receives less than $12,500 in Medicare revenues from the CLFS during a data collection period, the single laboratory would be an applicable laboratory with respect to its ADLT, which means its applicable information for the ADLT must be reported. However, because we want to minimize the data collection and reporting burden for laboratories to the extent we can, with respect to the other CDLTs the single laboratory furnishes that are not ADLTs, the low expenditure threshold will still apply. This means that the single laboratory offering and furnishing an ADLT that does not receive at least $12,500 in Medicare CLFS revenues is not an applicable laboratory with respect to its CDLTs that are not ADLTs, and it may not report information for those other CDLTs. For example, if the single laboratory that offers and furnishes an ADLT receives greater than 50 percent of its Medicare revenue from the CLFS and PFS during a data collection period but only receives $10,000 in revenues from the CLFS during the data collection period, it would be an applicable laboratory only for the purpose of reporting applicable information for the ADLT. The single laboratory that offers and furnishes an ADLT would not be an applicable laboratory for purposes of the other CDLTs it furnishes that are not ADLTs.

In this circumstance, the single laboratory would report applicable information for the ADLT during the data reporting period, but would not report applicable information for the other CDLTs it furnishes that are not an ADLT. However, if the single laboratory meets the majority of Medicare revenue threshold, that is, it receives greater than 50 percent of its Medicare revenues from the CLFS and PFS during a data collection period and also meets the low expenditure threshold, that is, it receives at least $12,500 in revenues from the CLFS during the data collection period, it would be an applicable laboratory for purposes of all of its CDLTs, that is, ADLTs and other CDLTs that are not an ADLT, and it would report applicable information for all of its tests during the data reporting period. We are revising our definition of applicable laboratory in § 414.502 accordingly. We are also adding the following statement to § 414.504(g) to account for our policy that may result in a single laboratory being an applicable laboratory with respect to its ADLTs but not with respect to its other CDLTs: For a single laboratory that offers and furnishes an ADLT that is not an applicable laboratory except with respect to its ADLTs, the applicable information of its CDLTs that are not ADLTs may not be reported.

Comment: Many commenters referenced a report by the Department of Health and Human Services Office of the Inspector General (OIG) entitled ''Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data.'' The commenters stated that the OIG report showed 19 percent of Medicare CLFS payments went to physician office laboratories, 24 percent went to hospital-based laboratories, and 57 percent went to independent laboratories. The commenters urged us to define applicable laboratory in a way that reflects the actual laboratory marketplace, consistent with the ratio identified by the OIG. One commenter stated that this ratio could be achieved by adjusting the low expenditure threshold up or down until the desired percentages are obtained.

Response: We do not agree with commenters that an applicable laboratory should be defined so as to achieve the ratio of physician office laboratories, independent laboratories, and hospital-based laboratories consistent with what the OIG report showed. We believe this approach would place an undue administrative burden on physician office laboratories. For instance, based on the findings from the OIG report, nearly 20 percent of all physician office laboratories would be applicable laboratories. Given that the new CLFS payment methodology is based on the weighted median private payor rate, it is unlikely that including additional small physician office laboratories would have a material impact on payment amounts; the analysis we used to establish the low expenditure threshold suggests that the volume from larger laboratories would dominate the market and therefore the determination of the weighted median private payor rate.

Comment: A few commenters urged us to establish a low volume threshold that would exclude end-stage renal disease (ESRD) laboratories from the definition of applicable laboratory. The commenters stated that almost all ESRD-related laboratory testing is bundled into a per-patient payment that Medicare pays directly to the dialysis facility, and the ESRD laboratory is paid by the dialysis facility for the bundled laboratory services they furnish to Medicare beneficiaries. The commenters noted that the only Medicare CLFS revenues ESRD laboratories receive directly are for laboratory tests that are not related to renal disease. The commenters contend that this small number of non-ESRD-related laboratory tests furnished to Medicare beneficiaries would result in the ESRD specialty laboratories being considered applicable laboratories, although they have little private payor data to report. One commenter stated that ESRD laboratories with Medicare CLFS test volume of less than 5 percent of their total test volume for Medicare patients should be excluded from the definition of applicable laboratory. However, the same commenter also supported the majority of Medicare revenues threshold requiring at least 50 percent of total Medicare revenues be derived from the PFS and CLFS, which the commenter believes reflects the reality of accounting for Medicare revenues related to the ESRD PPS.

Response: We established the low expenditure threshold, in part, to alleviate the reporting burden on small laboratories that are likely to have a relatively low volume of CLFS claims. We believe the application of the majority of Medicare revenues threshold criterion, along with the low expenditure threshold, would exclude ESRD laboratories whose Medicare laboratory revenues are mostly derived from the ESRD PPS. However, we would not want to exclude an ESRD laboratory from the definition of applicable laboratory if it receives CLFS revenues greater than the established low revenue threshold. Therefore, we are not developing a low volume threshold specific to ESRD laboratories.

1. Low Expenditure Threshold

As discussed in the proposed rule (80 FR 59393 through 59394), we established a low expenditure threshold to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a test, and minimizing the reporting burden for laboratories that receive a relatively small amount of revenues under the CLFS. The proposed low expenditure threshold would have required an entity to receive at least $50,000 of its Medicare revenue from the CLFS for a data collection period to be considered an applicable laboratory. We established that threshold based on CY 2013 TIN-level Medicare CLFS claims. We also proposed an initial data collection period of July 1, 2015, through December 31, 2015 (with all subsequent data collection periods being a full calendar year). In conjunction with the shortened initial data collection period, we proposed a $25,000 low expenditure threshold, whereas for all subsequent data collection periods, we proposed a low expenditure threshold of $50,000.

Although we are not revising the low expenditure threshold in response to the public comments we received on the issue, we are revising it in conjunction with our decisions to define applicable laboratory in terms of the NPI rather than the TIN and, as discussed in section III.D., to make the data collection period 6 months rather than a full calendar year.

To establish the new low expenditure threshold amount, we repeated the analysis we used for the proposed rule, but using NPI-level claims data rather than TIN-level claims data. We reviewed Medicare payment amounts from CY 2013 Medicare CLFS claims for physician office laboratories and independent laboratories at the NPI level. We assessed the number of billing physician office laboratories and independent laboratories that would otherwise qualify as applicable laboratories based on the majority of Medicare revenues threshold, but that would be excluded from the definition under various low expenditure revenue thresholds. Consistent with our analysis for the proposed low expenditure threshold, we did not include hospitals whose Medicare revenues were primarily under section 1833(t) of the Act for outpatient services and section 1886(d) of the Act for inpatient services, as these entities are unlikely to meet the definition of applicable laboratory. We found that, with a $25,000 annual

revenue threshold, the exclusion of data from physician office laboratories and independent laboratories with total CLFS revenues below that threshold, did not materially affect the quality and sufficiency of the data we needed to set rates. As we found for the proposed rule, we were able to substantially reduce the number of laboratories qualifying as applicable laboratories (that is, approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories) while retaining a high percentage of Medicare utilization (that is, approximately 92 percent of CLFS spending on physician office laboratories and approximately 99 percent of CLFS spending on independent laboratories).

Additionally, because we are changing the data collection period from a full calendar year to 6 months in this final rule, we reduced the $25,000 annual low expenditure threshold by 50 percent, which resulted in a $12,500 low expenditure threshold for the 6-month data collection period. Accordingly, any laboratory that would otherwise be an applicable laboratory, but that receives less than $12,500 in CLFS revenues in a data collection period would not be an applicable laboratory (with the exception of single laboratories that offer and furnish ADLTs, which would be considered applicable laboratories only with respect to the ADLTs that they offer and furnish). As discussed previously in this section, we are finalizing the low expenditure threshold criterion as part of the definition of applicable laboratory in § 414.502. In addition, because the initial data collection period will no longer be shorter than subsequent ones, it is no longer necessary for us to apply a different low expenditure threshold to the initial data collection period. Therefore, we are removing the provision in the definition of applicable laboratory that would have distinguished the initial data collection period low expenditure threshold.

As with the proposed low expenditure threshold of $50,000, in determining whether its CLFS revenues in a data collection period are at least $12,500, a laboratory would not include Medicare payments made to hospital laboratories for tests furnished for hospital inpatients or hospital outpatients. In other words, a laboratory would need to determine whether its Medicare revenues from laboratory tests billed on Form CMS 1500 (or its electronic equivalent) and paid under the current CLFS (under section 1833(h) of the Act) and the revised CLFS (under section 1834A of the Act) are at least $12,500 for the data collection period. If a laboratory receives less than $12,500 in Medicare revenues for CLFS services paid on Form CMS 1500 (or its electronic equivalent) during a data collection period, the laboratory would not be an applicable laboratory.

Some laboratories will not know whether they meet the low expenditure threshold, that is, if they receive at least $12,500 in Medicare CLFS revenues in a data collection period, until after the data collection period is over; in that case, they would have to assess their total Medicare CLFS revenues during the 6-month window between the end of the data collection period and the beginning of the data reporting period. However, for many laboratories, it will be clear whether they exceed the low expenditure threshold even before the end of the data collection period. A laboratory would need to reevaluate its status as to the $12,500 low expenditure threshold for each data collection period, that is, every year for ADLTs and every 3 years for all other CDLTs.

B. Definition of Applicable Information

Section 1834A(a)(3) of the Act defines the term ''applicable information'' as (1) the payment rate that was paid by each private payor for a test during the data collection period, and (2) the volume of such tests for each such payor during the data collection period. Under section 1834A(a)(5) of the Act, the payment rate reported by a laboratory must reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1847A(c)(3) of the Act relating to a manufacturer's average sales price for drugs or biologicals. Section 1834A(a)(6) of the Act states that if there is more than one payment rate for the same payor for the same test, or more than one payment rate for different payors for the same test, the applicable laboratory must report each payment rate and corresponding volume for the test. Section 1834A(a)(3)(B) of the Act provides that applicable information must not include information about a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period.

We proposed to define applicable information in § 414.502 as, for each CDLT for a data collection period, each private payor rate, the associated volume of tests performed corresponding to each private payor rate, and the specific HCPCS code associated with the test, but not information about a test for which payment is made on a capitated basis.

Several terms and concepts in our proposed definition required explanation. First, we addressed the term ''private payor rate.'' The statutory definition of applicable information refers to ''payment rate'' as opposed to private payor rate; however, we often use payment rate generically to refer to the amount paid by Medicare under the CLFS. For the proposed rule, we believed it could be confusing to the public if we used the term ''payment rate'' as it related to both applicable information and the amount paid under the CLFS. Because the statute says the payment rate is the amount paid by private payors, we believed ''private payor rate'' could be used in the context of applicable information rather than payment rate. Therefore, we referred to the private payor rate in regard to applicable information, and we did so even when we were referring to the statutory language that specifically references payment rate. When we used the term ''payment rate,'' unless we indicated otherwise, we were referring to the Medicare payment amount under the CLFS. In our proposed definition of private payor rate, we attempted to be clear that we were limiting the term to its use in the definition of applicable information. We continue to use the term private payor rate with regard to applicable information in this final rule.

Regarding the definition of ''private payor rate,'' the statute indicates that applicable laboratories are to report the private payor rate ''that was paid by each private payor,'' and that the private payor rate must reflect all price concessions. The private payor rate, as we noted previously, is the amount that was paid by a private payor for a CDLT, and we proposed to incorporate that element into our proposed definition of private payor rate. To calculate a CLFS amount, we believed it was necessary to include in private payor rates patient deductible and coinsurance amounts. (Note: In the discussion below, ''patient'' refers to a privately insured individual while ''beneficiary'' refers to a Medicare beneficiary.) For example, if a private payor paid a laboratory $80 for a particular test, but the payor required the patient to pay the laboratory 20 percent of the cost of that test as coinsurance, meaning the private payor actually paid the laboratory only $64, the laboratory would report a private payor rate of $80 (not $64), to reflect the patient coinsurance. The alternative would be for private payor rates to not include patient deductibles and coinsurance (such policy would yield $64 in the above example). Thus, the issue of whether to include or exclude

patient deductible and coinsurance in the definition of private payor rate has a material effect on the private payor rate and, ultimately, the payment amount determined by CMS. As Medicare generally does not require a beneficiary to pay a deductible or coinsurance on CLFS services, we believed it was important for private payor rates to be reported analogous to how they will be used by CMS to determine the Medicare payment amount for CDLTs under the new payment methodology. For this reason, we proposed that applicable laboratories must report private payor rates inclusive of all patient cost sharing amounts.

With regard to price concessions, section 1834A of the Act is clear that the private payor rate is meant to reflect the amount paid by a private payor less any price concessions that were applied to a CDLT. For example, there may be a laboratory that typically charges $10 for a particular test, but offers a discount of $2 per test if a payor exceeds a certain volume threshold for that test in a given time period. If the payor exceeds the volume threshold, the private payor rate for that payor for that test, taking into account the $2 discount, is $8. The statute lists specific price concessions 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 requirement, chargebacks, and rebates (except for Medicaid rebates under section 1927 of the Act). These lists are examples of price concessions, and, we believed, were not meant to be exhaustive. We indicated that other price concessions that are not specified in section 1834A of the Act might be applied to the amounts paid by private payors, and we would expect those to be accounted for in the private payor rate. Within our definition of private payor rate, we proposed that the amount paid by a private payor for a CDLT must be the amount after all price concessions were applied.

We proposed to codify the definition of private payor rate in § 414.502. Specifically, we proposed that the private payor rate, for applicable information, is the amount that was paid by a private payor for a CDLT after all price concessions were applied, and includes any patient cost-sharing amounts, if applicable.

Next, we addressed the definition of ''private payor.'' Section 1834A(a)(3)(i) of the Act specifies that applicable information is the private payor rate paid by each private payor. Section 1834A(a)(8) of the Act defines private payor as (A) a health insurance issuer and a group health plan (as such terms are defined in section 2791 of the Public Health Service Act), (B) a Medicare Advantage plan under part C, and (C) a Medicaid managed care organization (as defined in section 1903(m) of the Act).

A health insurance issuer is defined in section 2791(b)(2) of the Public Health Service (PHS) Act, in relevant part, as an insurance company, insurance service, or insurance organization (including a health maintenance organization) which is licensed to engage in the business of insurance in a state and which is subject to state law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974 (ERISA)). We incorporated this definition of health insurance issuer into our proposed definition of private payor by referring to the definition at section 2791(b)(2) of the PHS Act.

Section 2791(a)(1) of the PHS Act defines a group health plan, in relevant part, as an employee welfare benefit plan (as defined in section 3(1) of ERISA to the extent that the plan provides medical care and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. We incorporated this definition of group health plan into our definition of private payor by referring to the definition at section 2791(a)(1) of the PHS Act.

A Medicare Advantage plan under part C is defined in section 1859(b)(1) of the Act as health benefits coverage offered under a policy, contract, or plan by a Medicare+Choice organization under, and in accordance with, a contract under section 1857 of the Act. In the proposed rule we incorporated this definition of Medicare Advantage plan into our definition of private payor by referring to the definition in section 1859(b)(1) of the Act.

A Medicaid managed care organization is defined in section 1903(m)(1)(A) of the Act, in relevant part, as a health maintenance organization, an eligible organization with a contract under section 1876 of the Act or a Medicare+Choice organization with a contract under Medicare Part C, a provider sponsored organization, or any other public or private organization, which meets the requirement of section 1902(w) of the Act and (i) makes services it provides to individuals eligible for benefits under Medicaid accessible to such individuals, within the area served by the organization, to the same extent as such services are made accessible to individuals (eligible for medical assistance under the State plan) not enrolled with the organization, and (ii) has made adequate provision against the risk of insolvency, which provision is satisfactory to the state, meets the requirements under section 1903(m)(1)(C)(i) of the Act (if applicable), and which assures that individuals eligible for benefits under Medicaid are in no case held liable for debts of the organization in case of the organization's insolvency. An organization that is a qualified health maintenance organization (as defined in section 1310(d) of the PHS Act) is deemed to meet the requirements of clauses (i) and (ii). We incorporated this definition of Medicaid managed care organization into our definition of private payor by referring to the definition at section 1903(m)(1)(A) of the Act.

We proposed to codify the definition of ''private payor'' in § 414.502 as a health insurance issuer, as 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.

Next, section 1834A(a)(3) of the Act requires that applicable information include the private payor rate for each test and the ''volume of such tests'' for each private payor. Regarding the volume reporting requirement, we are aware that sometimes laboratories are paid different amounts for the same CDLT by a payor. Also, sometimes laboratories are paid different amounts for the same CDLT by different payors. Section 1834A(a)(6) of the Act specifies that an applicable laboratory must report each such private payor rate and associated volume for the CDLT. Accordingly, we proposed that each applicable laboratory must report each private payor rate for each CDLT and its corresponding volume. For example, an applicable laboratory and private payor may agree on a volume discount for a particular test whereby the first 100 tests will be reimbursed at $100. The 101st test (and all thereafter) will be reimbursed at $90. In reporting to CMS, the laboratory would report two different private payor rates for this private payor. The first would be 100 tests at a private payor rate of $100 per test, and the second, $90 for all tests reimbursed thereafter. We proposed to implement the volume reporting requirement by including in the proposed definition of applicable

information in § 414.502 that, in addition to ''each'' private payor rate for ''each'' CDLT, applicable information is the associated volume of tests performed corresponding to each private payor rate.

In the proposed rule we discussed the need to be able to identify the particular test for which private payor information is being reported. As CLFS tests are identified by HCPCS codes (see 80 CFR 59403 to 59404 for discussion of coding), applicable laboratories will need to report a HCPCS code for each test that specifically identifies the test being reported. We proposed to include in § 414.502 that applicable information includes the specific HCPCS code associated with each CDLT. Some laboratory tests are currently billed using unlisted CPT codes or HCPCS level II miscellaneous/not otherwise classified (NOC) codes. Because NOC codes and unlisted CPT codes do not describe a single test and may be used to bill and pay for multiple types of tests, we would not be able to determine the specific laboratory test corresponding to a reported private payor rate if either was used for reporting. To ensure that applicable laboratories do not report applicable information with a NOC code or an unlisted CPT code, we also proposed to define ''specific HCPCS code'' in § 414.502 as a HCPCS code that does not include an unlisted CPT code, as established by the American Medical Association, or a NOC code, as established by the CMS HCPCS Workgroup. Therefore, data on tests that are billed using unlisted CPT codes or NOC codes would not be considered applicable information and would not be reported.

Finally, the statute specifies that applicable information does not include certain information listed in section 1834A(a)(3)(B) of the Act—information for a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period. A capitated payment is made for health care services based on a set amount for each enrolled beneficiary in the plan for a given period of time, regardless of whether the particular beneficiary receives services during the period covered by the payment. Payment is typically made on a capitated basis under a managed care arrangement. As there is no way to determine payment specifically for a given test, it cannot be reported as applicable information. Therefore, we proposed to specify in the definition of applicable information in § 414.502 that the term does not include information about a test for which payment is made on a capitated basis. We stated that we do not believe providing a discount based on volume of tests furnished is an example of a payment made on a capitated basis or other similar payment basis.

A discussion of the public comments we received on the definition of applicable information and our responses to those comments appears below.

Comment: Many commenters requested that we exclude private payor rates from the definition of applicable information that would be administratively burdensome, if not impossible, for applicable laboratories to report to CMS. Specifically, the commenters suggested that private payor rates that would not have any bearing on establishing the weighted median private payor payment rates, and would otherwise be immensely burdensome for laboratories to report, should be excluded from the definition of applicable information. The commenters contended that not including certain information as applicable information would not have a material effect on the weighted median private payor payment rates and would reduce the burden on applicable laboratories. They provided the following examples of payments that should be excluded from the definition of applicable information and therefore from reporting, if the laboratories so chose:

- Hard copy (manual) remittances where HCPCS-level payment data are not captured or the formatting of the hard copy remittance advice is not conducive to optical character recognition (OCR) scanning;
- Manual remittances where the payor has grouped test-level payments into an encounter-level (claim-level) payment;
- Payments that were made in error, which are often not corrected until months after the incorrect payment was received;
- Bulk settlements;
- Payments that include post-payment activity such as recoupments;
- Payments from secondary insurance payors;
- Payments that do not reflect specific HCPCS code-level amounts; and
- Other similar payments.

The commenters requested that we permit some measure of flexibility for applicable laboratories to exclude reporting the aforementioned items from applicable information where the administrative burden of collecting and reporting applicable information exceeds any potential to influence the final payment rate. To that end, the commenters requested that we issue subregulatory guidance after publication of the final rule to specify the information that laboratories may exclude from reporting.

Response: As discussed in the proposed rule (80 FR 59394), we proposed to define applicable information to mean each private payor rate for each CDLT in a data collection period, the associated volume of tests performed corresponding to each private payor rate, and the specific HCPCS code associated with the test, but not information about a test for which payment is made on a capitated basis. We proposed that private payor rate would mean, in part, ''the amount that was paid'' by a private payor.

First, the commenters' specific requests that certain information be excluded from the definition of applicable information indicate to us that we need to provide clarification about what we meant by the term ''paid'' in the proposed definition of private payor rate. We clarify here that an amount has been paid if the laboratory received final payment for the test. Many of the items commenters requested to be excluded would not be considered applicable information because final payment would not have been made for the test. For instance, a private payor pays a laboratory for a test, but subsequent post-payment activities may change that initial payment amount. Some examples of post-payment activity that could change the initial payment amount are the correction of an initial payment made in error or recoupment of payment. Where those types of activities result in a final payment, the resulting payment amount would be considered for purposes of the private payor rate if it is made to the laboratory in the data collection period. For example, if an initial claim was paid in error 3 months before a data collection period and then corrected, with final payment being made by the private payor during the data collection period, the final corrected payment amount for the test would be considered for purposes of the private payor rate. If a test is performed during a data collection period, but a final payment is not made until after the data collection period, that payment amount would not be a private payor rate for purposes of applicable information and, therefore, would not be reported to CMS. Final payments from secondary insurance payors would also be considered in calculating private payor rates if the final payment was made during the data collection period.

Second, commenters asked whether payment rates can be excluded from the

definition of applicable information if the payment does not reflect specific HCPCS code-level amounts. In the proposed rule (80 FR 59396), we explained that we need to be able to identify the particular test for which private payor information is being reported. Therefore, we proposed to require that applicable information includes the specific HCPCS code associated with each CDLT to prevent private payor rates corresponding to a HCPCS level II/not otherwise classified (NOC) code or an unlisted CPT code from being reported. Accordingly, if a laboratory cannot correlate a private payor payment amount to a specific HCPCS code, that amount is not a private payor rate for purposes of applicable information.

Third, commenters asked about excluding from applicable information manual remittances where the payor has grouped test-level payments into an encounter (claim-level) payment. The proposed rule specified that, for each CDLT, the associated volume of tests performed corresponding to each private payor rate is a component of the definition of applicable information. Where the associated volume of tests performed corresponding to each private payor rate cannot be discerned by a laboratory from the private payors' remittance, those payment amounts would not be considered applicable information and should not be reported to CMS. Therefore, where a private payor groups test-level payments into a claim-level payment, instead of by individual HCPCS code, those rates would not be applicable information.

Commenters also asked that we allow stakeholders to decide whether the burden of collecting and reporting certain payment rates outweighs the potential influence those rates would have on final payment rates and, when that is the case, stakeholders would not have to report it as applicable information. We cannot permit stakeholders to exercise that discretion. The statute is clear that applicable information, which is used to set CLFS payment amounts, must be reported for applicable laboratories for a data collection period, and it defines applicable information, in part, as the payment rate that was paid by each private payor for the test during a data collection period and the volume of such tests for each such payor for the data collection period. As such, we believe the statute does not support selective reporting of applicable information for applicable laboratories. If the laboratory meets the definition of applicable laboratory, the applicable information for that laboratory must be reported.

Comment: Many commenters raised questions about a variety of other issues regarding the definition of applicable information. They stated that the proposed rule does not clearly specify the dates that apply to private payor rates. For example, commenters asked whether private payor rate information collected during the data collection period is based on the date of payment, date of service, date of claim submission, or date of denial. The commenters stated that if the date of service is the controlling date, claims for laboratory services furnished during the data collection period may not be paid before the data collection period ends, which would mean the payment amounts would not qualify as private payor rates. These same commenters questioned whether denials, which they referred to as ''zero payments,'' are to be excluded from the data set reported to CMS. Many commenters requested clarification as to how to handle claims undergoing an appeal. Commenters also requested clarification as to whether the private payor rates collected include non-contracted amounts for out-of-network laboratories or services.

Response: As discussed in response to the previous comment, final payment must be made by the private payor for a laboratory test(s) during the data collection period for the rate to be considered in calculating a private payor rate. 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.

Where a 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 therefore not be used to determine a private payor rate. Payment rates for claims under appeal would only be private payor rates if the final payment amount is determined and paid during the data collection period. For example, if a laboratory filed an appeal for a test furnished prior to a data collection period, and the appeal was resolved so that final payment for the test was made during the data collection period, the final rate paid would be used to calculate the private payor rate. However, if the appeal was settled during the data collection period, but final payment was not made by the private payor until after the data collection period, the payment amount could not be used for a private payor rate and would therefore be excluded from applicable information.

Some commenters asked whether denials, which they referred to as zero payments, would need to be reported as applicable information because no private payor payment amount was made for the laboratory test(s). We assume commenters are suggesting that when a claim is denied, the payment amount for the test could be said to be zero dollars, so commenters want to know if, in those instances, they should report zero dollars as the private payor rate. Laboratories should not report zero dollars for CDLTs where a private payor has denied payment within a data collection period. We are revising the definition of private payor rate in § 414.502 to specify that it does not include information about denied payments.

Finally, in response to the commenters' request for clarification as to whether private payor rate includes non-contracted amounts for out-of-network laboratories or services, we clarify that applicable information includes private payor rates for out-of-network laboratories, as long as the final payment for the laboratory test was made by the private payor during the data collection period. As the statutory definition of applicable information does not distinguish between contracted and non-contracted amounts paid by private payors, we believe it is appropriate for the private payor rate to include non-contracted amounts paid to laboratories.

We are modifying the definition of applicable information in § 414.502 to clarify that, with respect to each CDLT, applicable information includes each private payor rate for which final payment has been made in the data collection period. We are also renumbering the provisions within the definition to make the requirements clearer; these are non-substantive changes that do not affect the final policy. In addition, we are modifying the definition of private payor rate in § 414.502 to clarify two points: (1) The private payor rate is the ''final amount'' that was paid by a private payor for a CDLT and; (2) as noted above, the private payor rate does not include information about denied payments.

Comment: Many commenters agreed with our proposal to include patient deductible and coinsurance amounts as part of the definition of private payor rate and our rationale for doing so. The commenters encouraged us to finalize our proposal to require applicable laboratories to report private payor rates that include patient cost sharing amounts.

Response: We agree with the commenters and are finalizing our proposed policy.

Comment: Two commenters stated that beneficiary cost sharing is frequently used to mean copayments and coinsurance, and recommended that we clarify our intent that private payor rate includes any patient cost sharing and deductible amounts if applicable.

Response: As discussed in the proposed rule (80 FR 59395), Medicare generally does not require a beneficiary to pay a deductible or coinsurance amount for services paid under the CLFS, and we believe it is important that private payor rates be reported analogous to how they will be used to determine the Medicare payment amount for laboratory tests under the new CLFS methodology. Therefore, we proposed that private payor rate includes all patient cost sharing amounts. For purposes of reporting applicable information under the CLFS, we clarify that private payor rate includes any patient cost sharing amounts required by private payors, including patient deductible amounts, coinsurance amounts (that is, the percentage of the fee schedule amount a private payor requires the patient to pay for a given laboratory test), and copayment amounts (that is, the specific dollar amount a private payor requires the patient to pay for a given laboratory test).

Comment: One commenter agreed with our proposal to include ''front-end concessions'' such as volume thresholds in private payor rates. However, the commenter stated that under the OIG's 1994 Special Fraud Alert and Medicare Claims Guidelines, providers, practitioners, or suppliers may forgive the deductible and copayments in consideration of a particular patient's financial hardship. The commenter believes that when the laboratory provides this type of ''one-off financial hardship'' discount, such concession should not be included in the private payor rate.

Response: Section 1834A(a)(5) of the Act requires the private payor rate to reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1847A(c)(3) of the Act. Accordingly, we proposed that the private payor rate is, among other things, the amount that was paid by a private payor for a CDLT after all price concessions are applied.

We are clarifying here that the price concessions to be applied are only those applied by the private payor. We do not intend that concessions applied by a laboratory, such as, for example, the waiver of patient coinsurance, copayments, or deductibles due to a patient's financial hardship, would be a price concession for purposes of the definition of private payor rate. The statute envisions that CLFS payment rates under the new system are based on the rates paid by private payors. Although laboratories may provide concessions to patients, we do not believe it is appropriate to factor those concessions into a system that is required to be based on the rates paid by private payors. We understand, however, that we may have created some confusion about which price concessions are to be applied and which are not. Unfortunately, we provided an example in the proposed rule of a discount provided by a laboratory, as opposed to a private payor, that would be considered to be a price concession. This example did not reflect our intent that, for the private payor rate, only price concessions made by the private payor are to be applied.

To be clear, concessions applied by a laboratory are not price concessions for purposes of the private payor rate. To clarify that only private payor price concessions apply in calculating the private payor rate and not those applied by the laboratory, we are modifying the definition of private payor rate in § 414.502 to indicate that, for purposes of applicable information, 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.

Comment: Many commenters raised questions as to whether private payor rates for laboratory tests paid only on the PFS should be reported, and requested that we publish a list of HCPCS codes for which we expect applicable laboratories to report applicable information.

Response: Only private payor payment rates for CDLTs paid for under the CLFS are considered for private payor rates. The 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. We will publish a list of HCPCS codes on the CLFS Web site for which applicable laboratories must report private payor rates as part of subregulatory guidance.

Comment: One commenter noted that the proposed rule only defines applicable information in terms of private payor rates. The commenter stated that if Medicare payments are not included, we would be neglecting to use the majority of payment rate information in determining the weighted median private payor payment amounts under the new CLFS.

Response: Section 1834A(a)(3) of the Act defines applicable information as the payment rate that was paid by each private payor, and section 1834A(a)(8) defines private payors to include health insurers, group health plans, Medicare Advantage plans under part C, and Medicaid managed care organizations. Therefore, we clarify that applicable information would include Medicare data to the extent it is collected from Medicare Advantage plans and reported to CMS.

Comment: One commenter suggested that the proposed regulations text be revised to refer to applicable ''rate'' information instead of applicable information.

Response: Section 414.502 defines applicable information as each private payor rate, the associated volume of tests performed corresponding to each private payor rate, and the specific HCPCS code associated with the test. We believe this is sufficient specificity for the industry to understand what applicable information is without adding the word ''rate'' to the term.

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

The statute applies different reporting and payment requirements to ADLTs than to other CDLTs, and further distinguishes a subset of ADLTs called ''new ADLTs.'' In this section, we discuss our definitions for the terms ''advanced diagnostic laboratory test'' and ''new advanced diagnostic laboratory test.''

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. Sections 1834A(d)(1) and (2) of the Act recognize special reporting and payment requirements for ADLTs for which payment has not been made under the CLFS prior to April 1, 2014 (PAMA's enactment date). In establishing a regulatory definition for ADLT, we considered each component of the statutory definition at section

1834A(d)(5) of the Act, and how we interpreted and incorporated key statutory terms and phrases.

We believe that, by including these provisions for ADLTs, the statute seeks to establish special payment status for tests that are unique and are provided only by the laboratory that developed the test, or a subsequent owner of that laboratory. In other words, we view the statute as intending to award special payment status to the one laboratory that is expending the resources for all aspects of the test—developing it, marketing it to the public, performing it, and selling it. It is with this understanding that we developed our proposed policies for defining ADLTs.

First, to be an ADLT, a test must meet the requirements specified in the first part of the definition at section 1834A(d)(5) of the Act, that is, it must be 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). For the meaning of ''single laboratory,'' we believed the statute intends to ensure that we grant ADLT status to the one laboratory that offers and furnishes the particular test, to the exclusion of all other laboratories. To ensure this is the case, we proposed to require the laboratory to be a facility with a single CLIA certificate as described in § 493.43(a) and (b) because we believed, in most instances, the laboratory's single CLIA certificate would correspond to one laboratory location or facility. Under our proposal, an entity with multiple CLIA certificates would not be a single laboratory. For example, 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 other ADLT criteria. Section 493.43(b) includes several narrow exceptions for certain types of laboratories that may have multiple locations.[1] We stated that we did not believe those exceptions would apply to most or all laboratories seeking ADLT status for a given test and, even if they did, we did not believe those particular exceptions would undermine our effort to identify the single laboratory offering and furnishing the ADLT.

Next, the statute directs that the test must be ''offered and furnished'' by a laboratory seeking ADLT status for the test. It also requires that the test be ''not sold for use by a laboratory other than the original developing laboratory.'' We interpreted the original developing laboratory referenced in the statute to be the same laboratory that offers and furnishes the test. This interpretation was consistent with our understanding that the statute intends for special payment status to be awarded to the one laboratory that is expending the resources for all aspects of the test. Within the two requirements—(1) that a laboratory seeking ADLT status must offer and furnish the test and (2) that the test is not sold for use by a laboratory other than the original developing laboratory—there were several components for us to parse, and we did so consistent with our view of the statutory intent. First, we stated that we believed a laboratory offers and furnishes a test when it markets and performs the test. The laboratory that markets and performs the test must also be the only one to sell it, that is, to receive remuneration in exchange for performing the test. In addition, we believed that laboratory must also be the one that developed the test, which means the laboratory designed it. We are aware that, in certain circumstances, a referring laboratory may bill for a test under section 1833(h)(5)(A) of the Act. The referring laboratory is a laboratory that receives a specimen to be tested and refers it to another laboratory, the reference laboratory, to perform the test. We explained that, in these situations, because the reference laboratory performed the test, it would be the laboratory that offered and furnished the test for purposes of the ADLT definition.

Accordingly, under our proposal, only one laboratory could design, market, perform, and sell the test. If more than one laboratory engages in any of those activities, the test would not meet the criteria to be an ADLT. Under our proposal, we would not expect to see more than one applicable laboratory report applicable information for a given ADLT.

Next, the statute permits a successor owner to the original developing laboratory to sell the test without disqualifying the test from ADLT status. We 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 (except for being the original developing laboratory). This means the successor owner is a single laboratory that markets, performs, and sells the ADLT.

In considering how to define successor owner, we looked to our regulations at § 489.18(a), which describe what constitutes a change of ownership for Medicare providers. Although laboratories are suppliers and not providers, we believed the language in this regulation appropriately applied to the wide range of potential changes in ownership for laboratories. Specifically, we proposed to incorporate the scenarios described in § 489.18(a) as discussed in the proposed rule, 80 FR 59397, as follows. A successor owner, for purposes of an ADLT, would mean a single laboratory that has assumed ownership of the laboratory that designed the test through any of the following circumstances:

- Partnership. In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable state law, constitutes change of ownership.
- Unincorporated sole proprietorship. Transfer of title and property to another party constitutes change of ownership.
- Corporation. The merger of the original developing laboratory corporation into another corporation, or the consolidation of two or more corporations, including the original developing laboratory, resulting in the creation of a new corporation constitutes change of ownership. However, a transfer of corporate stock or the merger of another corporation into the original developing laboratory corporation does not constitute change of ownership.
- Leasing. The lease of all or part of the original developing laboratory facility constitutes change of ownership of the leased portion. In the case of a lease, all of or part of the original developing laboratory is leased by the owner(s) of the original developing laboratory to another entity who takes over the continued production of the test, and the owner(s) of the original developing laboratory becomes the lessor of the laboratory where it formerly provided laboratory tests. In this situation, there would be a change of ownership of the leased portion of the laboratory, and the lessee would become the successor owner that could be paid for performing an ADLT, provided the test meets all other criteria for being an ADLT.

As we noted, the successor owner would need to be a single laboratory and meet all other aspects of the ADLT definition. For example, under our proposal, if an original developing

[1] Section 493.43(b) includes the following exceptions: (1) Laboratories that are not at a fixed location; (2) not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing; and (3) laboratories that are within a hospital that are located at contiguous buildings on the same campus and under common direction.

laboratory corporation is merged into another laboratory corporation that has multiple CLIA certificates, while the test would still be a CDLT, it would no longer be considered an ADLT. Under our proposal, we expected a laboratory that obtains CMS approval of ADLT status for a test 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. We proposed to define the terms ''single laboratory'' and ''successor owner'' in § 414.502.

Next, in addition to meeting the first part of the ADLT definition at section 1834A(d)(5) of the Act, the statute requires that an ADLT must meet one of the criteria described in paragraphs (5)(A), (5)(B), or (5)(C). Criterion A of section 1834A(d)(5) of the Act states that 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. We interpreted this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA. Tests that analyze nucleic acids (DNA or RNA) are molecular pathology analyses. Therefore, we proposed that, under criterion A, a test must be a molecular pathology analysis of DNA or RNA. Examples of such tests include those that analyze the expression of a gene, the function of a gene, or the regulation of a gene. The statute also requires that the test analyze ''multiple'' biomarkers of DNA, RNA, or proteins. Therefore, we stated that an ADLT might consist of one test that analyzes multiple biomarkers or it might consist of multiple tests that each analyzes one or more biomarkers.

That the analysis of the biomarkers must be ''combined with a unique algorithm to yield a single patient-specific result'' indicated to us that the algorithm must be empirically derived, and that the ultimate test result must be diagnostic of a certain condition, a prediction of the probability of an individual developing a certain condition, or the probability of an individual's response to a particular therapy. Furthermore, the statute requires the result to be a single patient-specific one, so we proposed that the test must diagnose a certain condition for an individual, or predict the probability that a specific individual patient will develop a certain condition(s) or respond to a particular therapy. We also proposed that the test must provide new clinical diagnostic information that cannot be obtained from any other existing test on the market or combination of tests (for example, through a synthesis of the component molecular pathology assays included in the laboratory test in question). We considered requiring that a new ADLT be clinically useful, as well as new, but decided against such a policy due to statutory limitations. These proposed policies for implementing criterion A were based on our view that ADLTs that meet the criterion are innovative tests that are new and different from any prior test already on the market and provide the individual patient with valuable genetic information to predict the trajectory of the patient's disease process or response to treatment of the patient's disease that could not be gained from another test or tests on the market. Finally, we stated that we expected an ADLT could include assays in addition to the biomarker assay(s) described above. For example, in addition to an analysis of a DNA biomarker, an ADLT might also include a component that analyzes proteins. We would not disqualify a test from ADLT status consideration if that is the case. In summary, we proposed that to qualify as an ADLT under criterion A of section 1834A(d)(5) of the Act, a test: (i) Must be a molecular pathology analysis of multiple biomarkers of DNA, or RNA; (ii) when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a 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; and (iv) may include other assays. We included this proposed requirement in paragraph (1) of the ADLT definition in § 414.502.

Criterion B of section 1834A(d)(5) of the Act states that the test is cleared or approved by the FDA. The FDA considers CDLTs to be medical devices, and has two main application processes for clearing and approving medical devices. To receive FDA clearance to market a new device, a Premarket Notification submission, also referred to as a 510(k), is submitted to FDA for review at least 90 days before introducing, or delivering for introduction, the device into interstate commerce. Before FDA can clear a 510(k) and allow a device to be commercialized, the 510(k) submitter must demonstrate that their medical device is ''substantially equivalent'' to a device that is legally marketed for the same intended use and for which a Premarket Approval Application (PMA) is not required. A request for FDA approval of a device is typically submitted through a PMA, which is the most stringent type of device marketing application required by FDA. A PMA refers to the scientific and regulatory review necessary to evaluate the safety and effectiveness of devices that have not been found to be substantially equivalent through the 510(k) [Premarket Notification] process or devices for which insufficient information exists to determine that general controls either alone (Class I) or together with special controls (Class II) would provide a reasonable assurance of their safety and effectiveness. To obtain FDA approval of a device, an applicant must submit a PMA which includes valid scientific evidence to assure that the device is safe and effective for its intended use(s). We further noted that FDA regulations or orders exempt many Class I and certain Class II devices from premarket notification and allow them to be legally marketed immediately without premarket clearance. Since criterion B of section 1834A(d)(5) of the Act requires FDA approval or clearance, we stated that we did not intend for this criterion to cover any devices that are, by regulation or order, exempt from premarket notification and that have not received FDA approval or clearance. We proposed that a laboratory test can be considered an ADLT if it is cleared or approved by the FDA and meets all other aspects of the ADLT definition. Under criterion B, laboratories would have to submit documentation of their FDA clearance or approval for the test. We stated that this process would be outlined through subregulatory processes prior to January 1, 2016.

To implement criteria A and B, we stated that we would establish guidelines for laboratories to apply for ADLT status and submit documentation to support their application. For example, we indicated that if our proposed definition of criterion A is finalized, laboratories would have to submit to CMS evidence of their empirically derived algorithms and show how their test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. As we noted in section II.F. of the proposed rule (80 FR 59402), section 1834A(a)(10) of the Act provides for confidentiality of the information disclosed by a laboratory under section 1834A(a) of the Act. As this statutory provision is limited to ''this section'' (that is, section (a)), we believed it does not apply to section (d) of section 1834A of the Act, which relates to information provided to the Secretary to determine whether a test is an ADLT. While we stated that we do

not expect to make information in an ADLT application available to the public, that information is not explicitly protected from disclosure under the confidentiality provisions of the statute, nor is it explicitly protected from disclosure in response to a Freedom of Information Act (FOIA) request, as is information disclosed by a laboratory under section (a), per section 1834A(a)(11) of the Act. However, we noted that FOIA includes an exemption for trade secrets and commercial or financial information obtained from a person that is privileged or confidential. An ADLT applicant should be aware that information in an ADLT application may not be protected from public disclosure even if it is marked as confidential and proprietary. We indicated that we could not guarantee information marked as proprietary and confidential will not be subject to release under FOIA. While a party may mark information as confidential and proprietary, the information may be subject to disclosure under FOIA unless, consistent with FOIA exemption (b)(4), the information relates to trade secrets and commercial or financial information that is exempt from disclosure. The ADLT applicant would need to substantiate this confidentiality by expressly claiming substantial competitive harm if the information is disclosed and demonstrating in a separate statement how the release would cause substantial competitive harm pursuant to the process in E.O.12600 for evaluation by CMS (please see 80 FR 59402 through 59403 for further discussion of the confidentiality and public release of data).

Criterion C of section 1834A(d)(5) of the Act gives the Secretary the authority to establish and apply other similar criteria by which to determine that a test is an ADLT. We did not propose to exercise this authority; however we indicated that if we do so in the future, it would be through notice and comment rulemaking.

2. Definition of New ADLT

Section 1834A(d) of the Act is titled ''Payment for New Advanced Diagnostic Laboratory Tests.'' As previously discussed in this section, section 1834A(d)(1)(A) of the Act provides special payment rules for ADLTs for which payment has not been made under the CLFS prior to April 1, 2014, the enactment date of PAMA. Section 1834A(i) of the Act, titled ''Transitional Rule,'' provides that during the period beginning on April 1, 2014, PAMA's enactment date, and ending on December 31, 2016, for ADLTs paid under Medicare Part B, the Secretary shall use the methodologies for pricing, coding, and coverage in effect on the day before April 1, 2014, which may include crosswalking or gapfilling methods. We interpreted section 1834A(i) of the Act to mean that we must use the current CLFS payment methodologies for ADLTs that are furnished between April 1, 2014, and December 31, 2016.

Accordingly, we proposed to define a new ADLT as an ADLT for which payment has not been made under the CLFS prior to January 1, 2017. Any ADLT paid for under the CLFS prior to January 1, 2017, would be an existing ADLT and would be paid in accordance with the current regulations at 42 CFR part 414, subpart G, including gapfilling and crosswalking methodologies. In other words, there would be no new ADLTs until January 1, 2017, and they would be first paid on the CLFS using the payment methodology for new ADLTs proposed in § 414.522. We proposed to codify the definition of ''new ADLT'' at § 414.502 to mean an ADLT for which payment has not been made under the CLFS prior to January 1, 2017.

A discussion of the public comments we received on the definitions of ADLT and new ADLT and our responses to those comments appears below.

Comment: A few commenters disagreed with our proposal to require an ADLT to be ''marketed and performed'' by a single laboratory. The commenters noted that in defining an ADLT, the statute requires the test be ''offered and furnished'' by a single laboratory, and that requiring activities such as marketing and performing the test would go beyond the intent of Congress and place undue restrictions on the normal business practices of ADLT laboratories. The commenters stated that ''offered and furnished,'' when read in the context of the statutory definition of an ADLT, indicates that the single laboratory furnishes the test and does not sell it as a ''kit'' to other laboratories for those laboratories to offer and furnish. The commenters also explained that a small ADLT laboratory may partner with larger laboratories to provide marketing support while still performing and billing for its tests because of resource constraints. In this scenario, the test would be offered and furnished by a single laboratory, but it may not qualify for ADLT status under the proposed requirement that the single laboratory must market and perform the test. The commenters contend that the words ''offered and furnished'' are sufficiently clear and well understood in the Medicare program and that CMS does not need to complicate the definition by redefining it as ''marketed and performed.'' Thus, the commenters recommended using the statutory terms ''offered and furnished'' instead of ''marketed and performed.''

Response: We agree with commenters that our definition of single laboratory should not preclude a test that would otherwise qualify as an ADLT from being an ADLT simply because the single laboratory relies on a third party to market the test, although we do not think our definition would necessarily do that. Even though a single laboratory may hire another entity to market the test, the single laboratory would still be the entity expending the resources for the test.

In the proposed rule, we explained that we considered ''marketing'' to be an appropriate illustration of how we interpreted the term ''offer.'' Nonetheless, we agree that some marketing activities, such as developing and implementing a promotional strategy, may go beyond ''offering'' a test. What we were attempting to achieve with our proposal that the single laboratory must be the only laboratory to market and perform the test, was to ensure that the single laboratory was the entity expending the resources for all aspects of the test, in other words, the entity responsible for administering all aspects of the test. We are using the term ''offer'' rather than ''market'' in this final rule because we are convinced by commenters that the terms are not synonymous and, in fact, marketing goes beyond the scope of offering. If a laboratory offers a test, it is presenting the test for sale, which is consistent with our view that a single laboratory is the entity expending the resources and is responsible for administering all aspects of the test.

In addition, we used the term ''performed'' in the proposed rule to illustrate what we believe it means for a laboratory to furnish a test. While it is important for the industry to know how we interpret the term ''furnish,'' we understand the industry prefers we use the term ''furnish'' in the regulatory definition of ADLT. Therefore, we are revising our proposed definition of ADLT in § 414.502 to include the statutory terms ''offered and furnished'' rather than ''marketed and performed.''

Comment: Several commenters did not agree with our proposal to define a single laboratory as a facility with a single CLIA certificate. The commenters stated that our proposed definition of ''single laboratory'' does not comport with how laboratories operate, and would be an insurmountable barrier for many laboratories whose tests Congress

meant to include as ADLTs. They explained that one laboratory may expend resources for all aspects of the test, but that laboratory does not necessarily hold only one CLIA certificate. For example, a laboratory may have multiple sites, each with its own CLIA certificate, but furnishes the ADLT at only one of those sites. Or, due to higher than expected demand for its testing, a laboratory may have to open a new laboratory facility in which to perform testing, and that second facility would be required to obtain its own CLIA certificate because of its different mailing address or location. The commenters stated that, as long as the offering and furnishing laboratory does not sell the test for use by another laboratory, then the number of CLIA certificates the entity holds should not be relevant to whether a test can qualify as an ADLT. Therefore, they recommended that, for purposes of an ADLT, the definition of ''single laboratory'' be revised to mean a laboratory and its parent corporation, wholly-owned subsidiaries, and other entities under common ownership, as applicable.

Response: After reviewing the public comments on this issue, we agree that defining single laboratory by requiring the laboratory to administer every aspect of the test—offer, furnish, develop, and sell—at only one physical location, is inconsistent with how laboratories are structured and how they operate. As noted by the commenters, a corporate entity may consist of multiple laboratories and other entities under common ownership that have different functions, for instance a laboratory that offers and furnishes tests and other entities that perform research and development activities. Additionally, we believe it is possible that limiting the definition of single laboratory to a facility with a single CLIA certificate could, in some instances, impede beneficiary access to unique, innovative laboratory tests.

For these reasons, we are not adopting our proposal to define single laboratory as a facility with a single CLIA certificate. For purposes of an ADLT, we are revising the definition of single laboratory to mean a laboratory as defined in § 493.2 which furnishes the test, and that may also design, offer, and sell the test. The definition also includes the entities that own the laboratory or that the laboratory owns, which may design, offer, and sell the test; this includes other laboratories that may be owned by the single entity.

We believe this revised approach 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 aspects of the ADLT such as research and development. It will also allow an original developing laboratory that meets the definition of a single laboratory to continue to be a single laboratory if it chooses to expand its organization by acquiring new laboratory sites to meet increased demand for laboratory testing. Revising the definition of single laboratory to allow multiple laboratories located in different locations throughout the country, under common ownership, to furnish the test could also improve beneficiary access to innovative laboratory tests.

Although our revised definition will enable parts of the single laboratory organization other than its component laboratories to assume responsibilities such as developing (as we discuss above, we believe when a laboratory develops a test, it means the laboratory designs it), offering, and selling the test, only the laboratory parts of the single laboratory organization may perform the test. Therefore, our revised definition specifies that only laboratories, as defined in § 493.2, may furnish the ADLT.

We are revising the definition of single laboratory in § 414.502 to indicate that a single laboratory, for purposes of an ADLT, means the laboratory, as defined in § 493.2, which furnishes the test, and that may also design, offer, or sell the test and the entity that owns the laboratory and the entity that is owned by the laboratory which may design, offer, or sell the test.

Additionally, as discussed previously in this section, we proposed that a successor owner for purposes of an ADLT, means a single laboratory that has assumed ownership of the laboratory that designed the test through any of the following circumstances: Partnership; unincorporated sole proprietorship; corporation; or leasing. Under our revised definition of single laboratory, because each successor owner is an entity that assumes ownership of a single laboratory, the successor owner becomes the owner of the entire single laboratory organization, that is, the laboratory and the other entities the laboratory owns or is owned by. For example, if the single laboratory owns multiple laboratories and other entities, then a change in partnership or sole proprietorship, as described in the definition of successor owner, would have to apply to the entire single laboratory organization to qualify as successor ownership. In the case of a merger of the single laboratory into another corporation or its consolidation with two or more corporations that results in a new corporation, the entire single laboratory organization would need to be included in the corporate merger to qualify as successor ownership.

For changes in ownership resulting from leasing, we proposed (80 FR 59397) that the lease of all or part of the single laboratory organization would constitute a change in ownership of the leased portion. However, we cannot reconcile leasing a portion of a single laboratory with our final policy that a single laboratory includes the laboratory and the other entities that own or are owned by the laboratory. Therefore, we are removing leasing from the definition of successor owner as a circumstance under which there can be a successor owner.

In addition, in the proposed rule we indicated that a successor owner for purposes of an ADLT means a single laboratory that has assumed ownership of the laboratory that designed the test. We recognize that successor ownership is not limited to just the successor of the original developing laboratory. There can be successor owners to successor owners. Therefore, we are revising the definition of successor owner to clarify, 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;

(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. We also specify that a transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

Comment: One commenter stated that the proposed definition of a ''successor owner'' does not include a laboratory that acquires the license to an ADLT that was ''discovered'' by a different entity. Specifically, the commenter explained that a number of ADLTs may be discovered by academic researchers who own the intellectual property rights

to a test such as a multi-analyte assay with algorithmic analysis. In these instances, the intellectual property rights would belong to the sponsoring institution and in many cases, the institution is incapable of further developing and validating the test or making it commercially available to the general public, or does not wish to do so. Some of the reasons given by the commenter for why the academic institution may not bring the test to market include, lack of capital, lack of support from the institution's laboratory or other facilities, and lack of infrastructure. In such cases, the commenter stated, the institution would license the intellectual property rights to another entity that develops the test for commercialization, and performs clinical trials to demonstrate analytic and clinical validity and clinical utility. The commenter contends that, even though this entity would only be a licensee, it is responsible for developing and validating the test in its own laboratory and therefore should be viewed as the successor owner for purposes of the definition of ADLT. Further, the commenter urged CMS to confirm that, a laboratory that obtains the exclusive license to the intellectual property rights for one or more uses of a test from the laboratory that ''discovered'' the test is also a successor owner.

Response: An academic institution that creates a test but does not fully develop it for use by the public would not be considered the original developing laboratory if it is not a laboratory under § 413.2, and if it does not design, sell, offer, and furnish the test, it would not meet the requirements of a single laboratory in the definition of ADLT.

The commenter describes a situation wherein an academic institution licenses the intellectual property to another entity that further develops the test for commercialization. We believe that by ''discovering'' the test, the academic institution partially develops the test. For instance, a laboratory that purchases the intellectual property of the test may rely on the academic institution to develop a method the test utilizes or a particular reagent the academic institution has patented. In such situations, 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. It also could not be a successor owner if the academic institution is not the original developing laboratory or a single laboratory. As such, the test would not qualify for ADLT status.

Comment: Many commenters did not agree with our proposal to exclude protein-only tests under criterion A of the definition of an ADLT. The commenters stated that our proposal would exclude tests that are solely comprised of proteins from being considered an ADLT, despite statutory language that explicitly includes protein biomarker analysis under criterion A. The commenters contend that protein-only diagnostics are being used to impact patient care today, and there is no reason why complex protein-only tests should not be eligible to be considered ADLTs. For example, one commenter stated that multi-analyte protein-based tests are valuable drivers of innovation in the field of precision medicine and in many cases, provide information about a patient's disease state that is more detailed and/or advanced than what may be drawn from DNA- or RNA-based tests. Another commenter explained that a great deal of innovation is occurring with multi-analyte protein-based assays with algorithmic analyses, for instance, assays for lung nodule cancer determination, autism diagnosis, and prostate cancer metastasis risk. The same commenter stated that our proposed policy is based on a misinterpretation of the statutory language and would block innovators from using an important pathway to bring these clinically impactful assays to market. Commenters also noted that the Advisory Panel on CDLTs unanimously recommended that we revise our proposal to reflect the statutory language and include protein-only tests in the definition of an ADLT. Therefore, the commenters strongly urged us to revise criterion A of the proposed definition of an ADLT to permit tests that are solely comprised of proteins to be eligible for ADLT status.

Response: We agree that complex protein-only tests may provide information about a patient's disease state that is more comprehensive and/or advanced than what may be obtained from DNA- or RNA-based tests, and valuable innovation is occurring within multi-analyte protein-based assays, which would be consistent with our view that ADLTs are innovative tests that are new and different from any prior test already on the market. Therefore, we agree that protein-only tests should be eligible for ADLT status under criterion A. Because ADLTs are advanced tests that are apt to be complex, however, we would expect only complex protein-only tests to qualify for ADLT status as discussed further below. Therefore, we are revising criterion A of the definition of an ADLT to include tests that are solely comprised of proteins.

In addition, we are not finalizing our proposal under criterion A that a test must be a molecular pathology analysis of multiple biomarkers of DNA or RNA. In the proposed rule (80 FR 59397 through 59398) we stated that tests that analyze nucleic acids (DNA or RNA) are molecular pathology analyses, and we therefore proposed that, under criterion A, a test must be a molecular pathology analysis of RNA or DNA. Because we are now including protein-only tests under criterion A, and protein-only tests are not molecular pathology tests, we are removing the requirement that an ADLT must be a molecular pathology test. The definition of ADLT in § 414.502(1)(i) is revised to state that it is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins.

Comment: Many commenters objected to our proposed definition of a ''unique algorithm,'' asserting that the statute requires the algorithm to be unique but not the result it produces. The commenters contend that the concept of ''unique'' only applies to the algorithm itself and not to the patient-specific result. Additionally, one commenter asserted that the statutory reference to a unique algorithm means that one ADLT must be different from other ADLTs. The same commenter stated that if a test comprises multiple biomarkers of DNA, RNA or proteins, incorporates an algorithm to provide a patient-specific result, and was developed by a single laboratory, there should be a presumption that the test comprises a unique algorithm because the test is the product of the development activities of the single laboratory. Another commenter stated that the statutory term ''single patient-specific result'' is sufficiently clear and does not require further interpretation, and that it would be unwise for us to be overly prescriptive in defining ADLT because it may prevent qualified tests from being considered ADLTs. Many commenters also mentioned that the Advisory Panel on CDLTs recommended that the definition of unique algorithm reflect the text of the statute. Therefore, the commenters recommended that we revise the definition of ADLT with respect to the unique algorithm to reflect the exact statutory language under criterion A.

Response: We considered the commenters' suggestion to use only the exact statutory language and not define unique algorithm as we proposed to do. However, we do not agree with this

approach for the following reasons. First, using only the exact language of the statute would leave the public without any specific guidance on how to interpret ''unique algorithm to yield a single, patient-specific result,'' and would leave us with no criteria by which to evaluate whether a test meets that requirement. Second, without such criteria, the requirement that a test have a ''unique algorithm to yield a single, patient-specific result'' would be, to some extent, self-determined by each laboratory requesting ADLT status. Without specific guidance, the laboratory seeking ADLT status would interpret the requirements under criterion A in whatever manner it chose, which could potentially vary depending on the test, and which could also vary from other laboratory interpretations. Third, if not further defined, the criterion could apply very broadly to nearly any test on the CLFS that is only done by one laboratory, which would be inconsistent with our view that ADLTs are innovative tests that are new and different from any test already on the market. Therefore, we believe it is necessary for us to interpret what it means for a unique algorithm to yield a single, patient-specific result, and to use that interpretation in establishing the requirements a test must meet to qualify as an ADLT. Additionally, as noted previously in this section, we are revising criterion A of the definition of an ADLT to include protein-only tests. However, we continue to have concerns about granting ADLT status for protein-only tests that are not advanced tests. To that end, we believe our proposed application of the unique algorithm requirement ensures that simple protein analyses would not be considered advanced tests as they are not likely to produce a patient-specific result that cannot be provided by any other test.

For the reasons discussed previously in this section, we are finalizing our proposal for the unique algorithm, and will reflect it in the definition of ADLT under criterion A as proposed.

Comment: One stakeholder urged us to remove the requirement that the test must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests. It contends that this requirement may limit competition among tests in the marketplace and allow an inferior test to monopolize the marketplace due only to its first-comer advantage.

Response: As noted previously, our view is that ADLTs are innovative tests that are new and different from any test already on the market, which is, in part, how we interpret the requirement that the test uses a unique algorithm. We indicated in the proposed rule (80 FR 59398) that our proposed requirements for criterion A, including that the test must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests, derive from our view of ADLTs. We do not believe the requirement, that the test must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests, will limit competition among tests and enable the test that is developed first to dominate the marketplace. For a new test(s) that is covered under Medicare Part B and that improves upon an ADLT, if that later test does not qualify as an ADLT, it would nonetheless be paid as a CDLT based on the median private payor rate methodology, as would the ADLT after the new ADLT initial period.

Comment: One commenter stated that Congress did not intend for information that results from the test to be new and otherwise unobtainable from any other test(s). The commenter believes this additional criterion is more suitable for a coverage determination than for a determination of whether a test qualifies as an ADLT.

Response: A Medicare coverage analysis for a given CDLT is a separate, independent process from the determination of ADLT status. Whereas a coverage analysis would evaluate whether a laboratory test is reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category), the ADLT application process will determine whether a test qualifies for special temporary payment status under the CLFS. Section 1834A(d)(5)(A) of the Act requires a test to yield a single patient-specific result. The requirement we are finalizing—that the test must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests—is the means by which we are implementing that statutory requirement. The policy is consistent with our overall view of ADLTs, and we believe it is appropriate and consistent with the statute.

Comment: One commenter stated that it appears an FDA-cleared or approved CDLT would qualify as an ADLT only if it was also offered and furnished by a single laboratory and not sold for use by a laboratory other than the laboratory that designed the test, or a successor owner of that laboratory. If that is the case, then FDA-cleared or approved tests that are designed, marketed, and distributed by manufacturers to multiple labs for ''off-the-shelf'' (for example, unmodified) use would not qualify as ADLTs. The commenter requested clarification in the final rule as to whether this interpretation is correct.

Response: The commenter is correct. In order to qualify for ADLT status, a test that is cleared or approved by the FDA must also be offered and furnished by a single laboratory and not sold for use by a laboratory other than the original developing laboratory or a successor owner. As discussed previously in this section, the definition of an ADLT consists of two parts. All tests must meet the first part of the definition which, as we note above, requires the test to be 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. All tests must also meet the second part of the definition, but the second part presents three alternative criteria, only one of which must be met (note, we are not implementing the third criterion, C, in this final rule). If a test is FDA-cleared or approved, but sold to multiple labs as a kit for ''off-the-shelf'' use, then the test is offered and furnished by more than a single laboratory and would not qualify for ADLT status.

Comment: One commenter recommended that we retain flexibility outside of the annual rulemaking process to implement criterion C of the definition of an ADLT. Specifically, the commenter urged us to consider allowing MACs to apply criterion C using criteria developed by CMS that would utilize the MACs' assessment of clinical, technological, and resource similarities to other tests that have already attained ADLT status. Another commenter urged CMS to create a simple process under criterion C to allow laboratories to apply for ADLT status for tests that do not meet criterion (A) or (B).

Response: We appreciate the suggestions for how we might establish additional criteria for determining ADLT status. As discussed previously in this section, we did not propose to exercise our authority to establish other criteria by which to determine ADLT status under criterion C of section 1834A(d)(5)(C) of the Act. If we decide in the future to exercise that authority, we would propose any additional criteria through notice and comment rulemaking so the public would have an opportunity to comment.

Comment: One commenter agreed with our proposal to define a new ADLT as an ADLT for which payment has not been made under the CLFS prior to January 1, 2017.

Response: As we discussed in the proposed rule, we interpreted two sections of the statute together to determine that new ADLTs would be ADLTs for which payment has not been made under the CLFS prior to January 1, 2017. Section 1834A(d)(1)(A) of the Act requires special payment for ADLTs for which payment has not been made under the CLFS prior to April 1, 2014 (the enactment date of PAMA). Section 1834A(i) of the Act provides that, between April 1, 2014 and December 31, 2016, we must price ADLTs using the methodologies in effect on March 31, 2014. Because the statute specifies the payment methodology for new ADLTs, which is not the methodologies in place as of April 1, 2014 (crosswalking and gapfilling), we reasoned that new ADLTs would be those tests first paid on the CLFS after December 31, 2016.

The proposed definition of new ADLT correlated to the proposed implementation date of the private payor rate-based CLFS, January 1, 2017. However, as we discuss in this final rule, in response to comments, we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. We believe it is also appropriate to adopt a corresponding change for new ADLTs because the statute requires new ADLTs to be paid based on private payor rates after the new ADLT initial period. If we were to retain the proposed implementation date for new ADLTs, it could result in a new ADLT receiving payment based on the median private payor rate before January 1, 2018. For example, if the initial period for a new ADLT were to end on September 30, 2017, payment would then be based on the weighted median private payor rate beginning October 1, 2017, which would be prior to the January 1, 2018 implementation schedule for the new private payor rate-based CLFS. Therefore, the January 1, 2018 implementation date will apply to CDLTs (that are not ADLTs), as well as new ADLTs. In conjunction with this change, the payment amount for existing ADLTs will be determined based on crosswalking and gapfilling for ADLTs furnished through December 31, 2017, instead of December 31, 2016.

We are revising the definition of new ADLT in § 414.502 to reflect that a new ADLT is an ADLT for which payment has not been made under the CLFS prior to January 1, 2018. We are also making a conforming revision to § 414.507(h) to indicate that the payment amount for ADLTs that are furnished between April 1, 2014, and December 31, 2017, is based on the crosswalking or gapfilling methods described in § 414.508(a).

Comment: A few commenters urged us to clarify the process for laboratories to pursue an ADLT designation. The commenters stated that the statutory definition of ADLT is straightforward and the application process should be equally straightforward to minimize the administrative burden. One commenter recommended that any application process by which laboratories would apply for ADLT status should consist of an objective checklist of the statutory criteria, and be submitted by ADLT applicants and reviewed by CMS on a quarterly basis.

Response: As discussed in the proposed rule, we plan to establish an application process for laboratories requesting ADLT status after publication of the CLFS final rule. The information laboratories will need to provide in their application will be consistent with the definition of ADLT in § 414.502. For example, we will provide instructions for how an ADLT applicant will need to demonstrate that the test is offered and furnished by a single laboratory and has not been sold for use by a laboratory other than the laboratory that designed the test, or a successor owner of that laboratory. We will also specify the information applicants must submit to demonstrate how the test meets the requirements of criterion A or criterion B. Additionally, we will specify the timeframes by which ADLT applications will be reviewed by us, how and when applicants will be notified of our decision, and the process by which an ADLT would receive a unique HCPCS code. We appreciate commenters' input that ADLT applications should be submitted and reviewed by us on a quarterly basis, and we will take that into consideration as we establish the schedule for requesting and approving ADLT status for a laboratory test. All of this detail will be provided through subregulatory guidance after the final rule is published.

Comment: Several commenters believe that Congress did not intend for a laboratory's confidential information to have to be provided to us for the agency to be able to determine whether a test meets the definition of an ADLT. They pointed to the statute, which did not confer explicit protection from disclosure under the Freedom of Information Act (FOIA) to ADLT information submitted to us, as it did in section 1834A(a)(11) of the Act for applicable information. Therefore, the commenters urged us to only require the submission of publicly available information that would describe the algorithm and assay, but would not require applicants to submit proprietary information about the algorithm and assay. Alternatively, the commenters requested that any proprietary information required by us, or included voluntarily by the ADLT applicant in its ADLT application, be automatically protected from public disclosure under 5 U.S.C. 552(b)(4) as a trade secret.

Response: As discussed in the proposed rule (80 FR 59398 through 59399), the statute provides for the confidentiality only of applicable information disclosed by a laboratory under section 1834A(a) of the Act. The confidentiality of information provision, section 1834A(a)(10) of the Act, does not apply to section 1834A(d) of the Act, which relates to the requirements a test must meet to be an ADLT. We explained, however, that information in an ADLT application might be protected from public disclosure, even though it is not explicitly protected from disclosure under the confidentiality provisions of the statute.

Specifically, we indicated that, although the statute does not explicitly protect ADLT application information from release under FOIA (as it does under section 1834A(a)(11) of the Act for applicable information), FOIA does include an exemption for trade secrets and commercial and financial information obtained from a person that is privileged or confidential. While we do not have the authority to provide automatic protection from public disclosure under this FOIA exemption, (b)(4), if an applicant submits an ADLT application that includes trade secrets or certain commercial or financial information, specified above, it is possible the information could be withheld from public disclosure under FOIA exemption (b)(4). An applicant that wishes to protect the information submitted in an ADLT application would mark it proprietary and confidential, and substantiate that statement by expressly claiming substantial competitive harm if the information is disclosed, and demonstrating 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 us. 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. However, we note that we would only be requiring information relevant to determining whether a test qualifies as an ADLT. Please see additional comments and responses related to confidentiality and

public release of data in section II.F. of this final rule.

D. Data Collection and Data Reporting

1. Definitions

Section 1834A(a) of the Act requires applicable laboratories to report applicable information. The information is gathered or collected during a ''data collection period'' and then reported to the Secretary during a ''data reporting period.'' Under the statute, the Secretary is to specify the period of time for the data collection period and the timeframe for the data reporting period. In this section, we proposed to define the terms ''data collection period'' and ''data reporting period.'' In determining what the proposed data collection and data reporting periods should be, we considered our objectives to: (1) Provide applicable laboratories sufficient notice of their obligation to collect and report applicable information to CMS; (2) allow applicable laboratories enough time to collect and report applicable information; (3) give CMS enough time to process applicable information to determine a CLFS payment rate for each laboratory test; and (4) publish new CLFS payment rates at least 60 days in advance of January 1 so laboratories will have sufficient time to review the data used to calculate CLFS payment rates and prepare for implementation of the new CLFS rates on January 1.

Section 1834A(a)(4) of the Act defines the term ''data collection period'' as a period of time, such as a previous 12-month period, specified by the Secretary. We believed the data collection period should be a full calendar year, for example, January 1 through December 31, because a full calendar year of applicable information would provide a comprehensive set of data for calculating CLFS rates. In addition, we chose to define a data collection period as a calendar year as opposed to, for example, a federal fiscal year (October through September), so the data collection period would coordinate with the timing of the CLFS payment schedule, wherein updated CLFS payment rates are in effect on January 1 of each year. We also believed the data collection period should immediately precede the data reporting period, which is the time period during which applicable laboratories must report applicable information to us. For example, the data reporting period for the 2018 data collection period (January 1, 2018, through December 31, 2018) would begin on January 1, 2019. We believed that having the data collection period immediately precede the data reporting period would result in more accurate reporting by laboratories and, thus, more accurate rate setting by us, because laboratories would have more recent experience, and therefore, be more familiar with the information they are reporting. Further, we believed that starting the data reporting period immediately after the data collection period would limit the lag time between reporting applicable information and the use of that applicable information to determine Medicare CLFS payments, thus ensuring that we are using the most recent data available to set CLFS payment rates. For these reasons, we proposed to codify in § 414.502 that the data collection period is the calendar year during which an applicable laboratory collects applicable information and that immediately precedes the data reporting period.

We proposed a different timeline for the 2015 data collection period, which would have begun July 1, 2015, and ended December 31, 2015. While our preference would have been for the data collection period to be a full calendar year, as we proposed for subsequent data collection periods, and for it to begin after publication of proposed and final rules implementing section 1834A of the Act, we believed the statute contemplated the possibility that the first data collection period would begin prior to publication of regulations establishing the parameters for data collection. Given that the statute, which was enacted on April 1, 2014, required us to establish the parameters for data collection through rulemaking by June 30, 2015, the first data collection period that would allow for reporting in 2016 and implementation of the new payment system on January 1, 2017, would have to have been in 2015. As the statute indicates that a data collection period could be a 12-month period, and data collection requirement regulations did not have to be complete until June 30, 2015, we believed the statute anticipated that the first data collection period would begin prior to publication of the June 30, 2015 regulations, that is, 6 months prior to a final regulation. In addition, section 1834A(a)(4) of the Act does not require the data collection period to be a 12-month period, but rather, suggests that it could be, and provides us the authority to determine the length of the period. Therefore, although we could have chosen to make the 2015 data collection period a full calendar year, given that laboratories would not have notice of the data collection period until our regulations were proposed and finalized, we believed it was reasonable to limit the time period of the first data collection period to 6 months, which would have been consistent with the length of time the data collection period would have been in effect prior to a final rule if we had adopted a full calendar year data collection period in 2015 and published regulations specifying that to be the case on June 30, 2015. While we believed a full calendar year of data would be the most robust and comprehensive for setting CLFS payment rates, we stated in the proposed rule that we believed the 6-month data collection period in 2015 would still provide sufficient, reliable data with which to set rates that accurately reflect private payor rates. Therefore, we proposed to include in the definition of data collection period in § 414.502 that the data collection period for 2015 would be July 1, 2015 through December 31, 2015.

Under section 1834A(a)(1) of the Act, beginning January 1, 2016, and every 3 years thereafter (or annually in the case of an ADLT), each applicable laboratory must report applicable information to the Secretary at a time specified by the Secretary. We believed applicable laboratories should have 3 months during which to submit applicable information from the corresponding data collection period, that is, the calendar year immediately preceding the data reporting period. For example, for purposes of calculating CY 2017 CLFS rates, the data collection period would have begun on July 1, 2015, and ended on December 31, 2015, and the data reporting period would have been January 1, 2016 through March 31, 2016. We believed a 3-month data reporting period would be a sufficient amount of time for applicable laboratories to report applicable information to us. As we explained in the proposed rule, it would give us adequate time to calculate CLFS payment amounts, upload the CLFS rates on Medicare's claims processing systems, and make that data publicly available (preliminarily in September and then a final version in November) before the CLFS rates would go into effect on the following January 1. Given the magnitude of the potential changes in CLFS payment rates, to give the industry sufficient time to prepare for the next year's fee schedule, we believed final CLFS rates for the following year should be published at least 60 days prior to the beginning of the next calendar year, or no later than November 1. For these reasons, we proposed that the definition of ''data reporting period'' in § 414.502 be the 3-month period during which an applicable laboratory reports applicable information to CMS and that

immediately follows the data collection period.

Table 1 illustrates the proposed data collection period, data reporting period, and CLFS rate year for which the data would have been used for CDLTs.

TABLE 1—PROPOSED DATA COLLECTION AND REPORTING PERIODS FOR CDLTS

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 3rd subsequent calendar year	Continues every 3rd subsequent calendar year.	New CLFS rate every 3rd year for 3 years.

As indicated in this section, we proposed that applicable information must be reported annually for ADLTs and follow the above proposed data collection schedule on an annual basis after the first data collection period, which would be for the first and second quarters of the new ADLT initial period, and reported to us by the end of the second quarter of the new ADLT initial period (described in more detail later in this section).

2. General Data Collection and Data Reporting Requirements

Section 1834A(a)(1) of the Act requires applicable laboratories, beginning January 1, 2016, to report applicable information on CDLTs that are not ADLTs every 3 years, and every year for ADLTs, at a time specified by the Secretary. As we discussed previously, we proposed that the data collection period during which applicable laboratories collect applicable information would be the calendar year immediately prior to the data reporting period. Thus, the data reporting period is a 3-month period that would occur each year for ADLTs, from January 1 through March 31, and every third year, from January 1 through March 31, for all other CDLTs (for example, 2016, 2019, 2022, etc.). We proposed to establish these data reporting requirements in § 414.504(a).

Section 1834A(a)(3)(A) of the Act requires applicable information to be the rate paid by each private payor for the test and the associated volume of such tests for each such payor during the data collection period. In addition, section 1834A(a)(6) of the Act specifies that, in the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory must report each such payment rate and the volume for the test at each such rate. Furthermore, section 1834A(a)(6) of the Act provides that, beginning January 1, 2019, the Secretary may establish rules to aggregate reporting, that is, permit applicable laboratories to combine the prices and volumes for individual tests. We explained that we understand this to mean that, absent rules set by the Secretary (in 2019 or later), applicable laboratories may not aggregate data by laboratory test in reporting applicable information. Taken together, these provisions indicated to us that an applicable laboratory must report applicable information for every test it performs for each private payor, including both the amounts paid and volume. This means, should a rate for a private payor change during the data collection period, an applicable laboratory would report both the old and new rates and the volume of tests associated with each rate. We realized the amount of applicable information could be voluminous for those applicable laboratories that offer a large number of tests. However, we believed the statute requires comprehensive reporting of applicable information so the Medicare CLFS rates accurately reflect the rates paid by private payors to laboratories. Our proposed definition of applicable information in § 414.502 states that applicable information, with respect to each CDLT for a data collection period, includes each private payor rate and the associated volume of tests performed corresponding to each private payor rate, so our proposed requirement at § 414.504(a) covers the requirement for applicable laboratories to report the private payor rate for every laboratory test it performs, and to account for the volume of tests furnished at each rate. We explained that this requirement means an applicable laboratory that has more than one payment rate for the same payor for the same test, or more than one payment rate for different payors for the same test, must report each such payment rate and the volume for the test at each such rate.

To minimize the reporting burden on applicable laboratories and to avoid collecting personally identifiable information, we proposed that we would only require applicable laboratories to report the minimum information necessary to enable us to set CLFS payment rates. We indicated that we would specify the form and manner for reporting applicable information in guidance prior to the first data reporting period, but generally, in reporting applicable information, we would expect laboratories to report the specific HCPCS code associated with each laboratory test, the private payor rate or rates associated with the HCPCS code, and the volume of laboratory tests performed by the laboratory at each private payor rate. We would not permit applicable laboratories to report individual claims because claims include more information than we need to set payment rates and they contain personally identifiable information. We also would not permit applicable laboratories to report private payor names because section 1834A(a)(11) of the Act prohibits a payor from being identified on information reported by the applicable laboratory. Our guidance would reflect these instructions. Accordingly, we proposed to include in our data reporting requirements at § 414.504(b), that applicable information must be reported in the form and manner specified by CMS.

3. 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, but does not specify when this initial period of 3 quarters begins. We believed the initial period should start and end on the basis of a calendar quarter, so 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 (for example, January 1 and March 31, April 1 and June 30, July 1 and September 30, or October 1 and December 31). We proposed this policy to be consistent with how applicable information would be reported for CDLTs (on the basis of a calendar year, that is, 4 quarters of applicable information) and how CLFS payment rates would be updated (also on the basis of a calendar year). We explained in the proposed rule that this

consistency is important so that after the new ADLT initial period is over, all CLFS payment rates (for CDLTs and ADLTs) would be posted publicly at the same time. Further, CMS updates all of its payment systems on the basis of a calendar quarter, and we believed consistency with all other CMS data systems would facilitate implementation and updates to the CLFS. Beginning and ending the new ADLT initial period on the basis of a calendar quarter would also be consistent with average sales price reporting for Medicare Part B drugs under section 1847A of the Act and desirable for the reasons stated above. If we were to start the initial period during a calendar quarter, then the end of the Q2 (the time by which applicable laboratories must report applicable information for new ADLTs) would also occur during a calendar quarter, which would mean applicable laboratories would be reporting applicable information for new ADLTs during a calendar quarter. Further, if an initial period of 3 quarters ended during a calendar quarter, we would have to begin paying for the ADLT using the methodology under section 1834A(b) of the Act during a calendar quarter. For these reasons, we proposed to start the initial period on the first day of the first full calendar quarter following the first day on which a new ADLT is performed. We proposed to refer to the initial period for new ADLTs as the ''new ADLT initial period,'' and to codify the definition in § 414.502.

Section 1834A(d)(2) of the Act requires applicable laboratories to report applicable information for new ADLTs not later than the last day of the Q2 of the initial period. The applicable information will be used to determine the CLFS payment amount (using the weighted median methodology; see our discussion of the proposed CDLT payment methodology at 80 FR 59404 through 59406) for a new ADLT after the new ADLT initial period. We proposed to codify the reporting requirement for new ADLTs in § 414.504(a)(3).

We provided the following as an example of the proposed reporting and payment schedule for a new ADLT: A new ADLT that is first performed by an applicable laboratory during the Q1 of 2017 (for example, February 4, 2017) would start its initial period on the first day of the Q2 of 2017 (April 1, 2017). The new ADLT initial period would last for 3 full quarters, until the end of the Q4 of 2017 (December 31, 2017). The applicable laboratory would be required to report applicable information for the new ADLT by the end of the Q2 of the new ADLT initial period, which would be, in this example, the end of the Q3 of 2017 (September 30, 2017). These data would be used to calculate the payment amount for the new ADLT, which would be applied after the end of the new ADLT initial period, or starting Q1 2018 (January 1, 2018). This payment amount would last through the remainder of CY 2018. The new ADLT would then follow the annual reporting schedule for existing ADLTs, that is, CY 2017 applicable information would be reported between January 1, 2018 through March 31, 2018, and the applicable information would then be used to establish the payment amount for the ADLT that takes effect on January 1, 2019.

Table 2 illustrates the proposed data collection and reporting periods for a new ADLT using the above example.

TABLE 2—PROPOSED DATA COLLECTION AND REPORTING PERIODS FOR NEW ADLTS

ADLT first performed	Initial period	Data collection period	Data reporting period	Used for CLFS rate year
02/04/2017	04/01/2017–12/31/2017	04/01/2017–09/30/2017 .... 01/01/2018–12/31/2018	By 09/30/2017 ..... 01/01/2019–03/31/2019	2018–2019. 2020.

A summary of the comments we received on the proposals for data collection and reporting and our responses are discussed below.

Comment: Many commenters urged us to move the implementation date of the private payor-based rates for the CLFS to January 1, 2018. The commenters stated that a January 1, 2017 implementation date does not allow sufficient time following release of a final rule for laboratories to build their information systems to collect, assess, and report the required data. The commenters contended that insufficient lead time could result in inaccurate reporting and increase their risk of being sanctioned with civil monetary penalties. Another commenter stated that the proposed implementation schedule does not provide an adequate amount of time for us to thoughtfully consider recommendations by stakeholders and, if necessary, develop modifications to the rule. The same commenter stated that laboratories subject to reporting may not have adequate time to prepare for reporting, especially in the absence of the regulatory guidance that we would release at a later date.

The commenters suggested that a January 1, 2018 implementation date would provide applicable laboratories sufficient notice of their obligation to collect and report applicable information and adequate time to collect and report the information to us. They asserted that moving the implementation date out by 1 year would also allow us enough time to process the private payor data and calculate and publish the new CLFS rates at least 60 days prior to implementation. In addition, many commenters stated that the recommendation to move the implementation date of the new system to January 1, 2018 is consistent with PAMA, which required us to publish a final rule by June 30, 2015 to enable new rates to be in effect on January 1, 2017, thereby contemplating an 18-month period from the date of the final rule to the implementation of the new rates.

Response: We recognize that entities will need sufficient time after the publication of the final rule to build the information systems necessary to collect private payor rates, and review and verify the data collected to ensure their accuracy. We understand that a moving the implementation date to January 1, 2018 would allow for those activities as well as independent validation testing of our system to which reporting entities will report applicable information and could also provide laboratories time to perform end user testing prior to the data reporting period. A January 1, 2018 implementation date would also allow laboratories to complete the registration processes for submitting applicable information well ahead of the data reporting period. We also appreciate that stakeholders are particularly concerned about having sufficient time to prepare for the new CLFS in light of the potential for civil monetary penalties. For all of these reasons, we agree with the commenters that we should move the implementation date of the new CLFS. As the majority of commenters indicated a January 1, 2018 implementation date would be sufficient, we are moving the

implementation date of the new CLFS to January 1, 2018. We are revising the data reporting schedule accordingly at § 414.504(a)(1) and (2) to require that, for CDLTs and ADLTs that are not new ADLTs, the data reporting period is a three-month period that occurs every 3 years beginning January 1, 2017.

Comment: We received comments from stakeholders requesting a January 1, 2019 implementation date for the revised CLFS. The commenters stated that moving the implementation date to January 1, 2019 would allow us enough time to finalize the rule and related guidance and for community laboratories to build systems and processes as necessary for compliance. The commenters recommended that the initial data collection period should be the first 6 months of 2017 (January 1, 2017 through June 30, 2017) and the initial data reporting period should be January 1, 2018 through March 31, 2018, with private payor-based rates effective on January 1, 2019. The commenters urged us to recognize the immense challenges many laboratories, particularly small and mid-size community laboratories, will face in implementing the new requirements while also maintaining their regular business practices of providing and billing for laboratory testing services.

Response: We considered moving the implementation date of the revised CLFS to January 1, 2019. However, based on the majority of comments we received on this issue, we are convinced that a January 1, 2018 implementation date is sufficient for laboratories to develop the necessary information systems to collect private payor rates and report applicable information. We note that, as discussed in section II.A., the low expenditure threshold will exclude laboratories that receive a relatively small amount of revenues under the CLFS from the definition of applicable laboratory. Therefore, we believe many of the community and physician office laboratories that would prefer that we implement the revised CLFS beginning January 1, 2019 will not meet the definition of applicable laboratory and will be excluded from the data reporting requirements.

Comment: Many stakeholders requested that we revise the data collection period from a full calendar year to 6 months and that we include a 6-month window between the end of the data collection period and the beginning of the data reporting period. The commenters explained that laboratories will need a minimum of 6 months to determine whether they are applicable laboratories for purposes of reporting private payor rates and if they are, to collect, format, organize, validate, and submit their data. The commenters contend that a 6-month window between the end of the data collection period and the beginning of the data reporting period will allow laboratories, which have no experience collecting and reporting private payor data to us, the necessary time to reconcile payment information with a multitude of private payors and review the accuracy of the collected data prior to submission. Commenters also recommended all data collection periods, both initial and subsequent, be 6 months instead of a full calendar year. One laboratory organization, which supported a 6-month data collection period followed by a 6-month gap before the data reporting period, commented that it performed its own analysis and found the weighted median payment amounts derived from 6 months of private payor data to be ''generally consistent'' with the weighted median private payor rates derived from a full year of data. Given these findings, the commenter believed we would be able to capture the data we need to calculate accurate market-based Medicare payment rates with a 6-month data collection period.

Response: We recognize that the data collection and reporting requirements in this final rule are new requirements with which the industry has no experience yet, and we understand the commenters' concerns that ample time be allotted for laboratories to review and verify the data collected before reporting it to us. We believe giving laboratories a 6-month period of time between the data collection and reporting periods will lead to higher quality data because laboratories will have the opportunity to ensure the data are complete and accurate. Additionally, as discussed in the proposed rule (80 FR 59400), although we believe a full calendar year of data would provide us with a robust and comprehensive dataset for determining CLFS payment rates, we also believe a 6-month data collection period will provide sufficient, reliable data on which to accurately set rates. Therefore, we are revising the data collection period as stakeholders suggest.

After we begin to obtain applicable information under the new private payor rate-based CLFS, we will evaluate the quality and quantity of applicable information reported in a 6-month data collection period. We will also evaluate whether a 6-month window before the reporting period continues to be necessary once the laboratory industry has more experience with the new CLFS. If we determine that a longer data collection period is necessary or appropriate, or that a 6-month period after the data collection period is no longer needed, we may propose modifications to our policies, which we would do through notice and comment rulemaking.

We are finalizing a 6-month data collection period, from January 1 through June 30, for all data collection periods, initial and subsequent. Because we are moving the implementation of the new CLFS to January 1, 2018, we no longer need to provide a shortened time frame for the initial data collection period, so we are no longer distinguishing the initial data collection period from subsequent data collection periods in the definition of data collection period in § 414.502. We are also finalizing the proposed 3-month data reporting period, from January 1 through March 31, for a data reporting period following a data collection period. This means entities will have six months between the end of the data collection period and the beginning of the data reporting period. We are revising the definition of data collection period in § 414.502 to read: Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period.

Table 3 illustrates the final data collection and reporting periods, as described above, and the CLFS rate year for which the data will be used for CDLTs.

TABLE 3—FINAL DATA COLLECTION AND REPORTING PERIODS FOR CDLTS

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.

Comment: One commenter, that also urged us to implement the new CLFS on January 1, 2018, recommended that CMS implement the new ADLT payment methodology on January 1, 2017 as proposed. Additionally, the commenter stated that assignment of specific codes for ADLTs should proceed on time as intended by statute. The commenter contends that, because data collection for new ADLTs would not begin until 2017, delaying implementation of the new ADLT payment methodology is not necessary to accommodate any change we might adopt in reporting for existing ADLTs and CDLTs.

Response: As discussed in section II.A. of this final rule, the proposed definition of new ADLT correlated to the proposed implementation date of the private payor rate-based CLFS, January 1, 2017. As we discuss previously in this section, in response to comments, we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. We believe it is also appropriate to adopt a corresponding change in the implementation date for new ADLTs because the statute requires new ADLTs to be paid based on private payor rates after the new ADLT initial period. If we were to retain the proposed implementation date for new ADLTs, conceivably, they could start being paid based on the median private payor rate before the revised CLFS is implemented. For example, if a new ADLT initial period were to end on September 30, 2017, payment would be based on the weighted median private payor rate beginning October 1, 2017, which would be prior to the January 1, 2018 implementation schedule for the new private payor rate-based CLFS. Therefore, the January 1, 2018 implementation date will apply to CDLTs, including ADLTs. We are modifying the definition of a new ADLT in § 414.502 to specify that a new ADLT is an ADLT for which payment has not been made under the CLFS prior to January 1, 2018.

Comment: Several commenters urged us to revise our proposed definition of new ADLT initial period to ensure that private payor rates can be reported and used to develop market-based rates for new ADLTs after the new ADLT initial period is over. The commenters stated that using the date a test is first performed as the starting point for determining when the new ADLT initial period begins may result in insufficient private payor data being reported to us. The commenters also stated that if the new ADLT initial period were to begin prior to Medicare coverage for the test (which one commenter suggested could take 6 to 12 months or longer), the time during which the new ADLT can be paid the actual list charge rate could expire before Medicare pays at that rate, which the commenters contended would defeat the purpose of the statutory provision creating a specific payment scheme for new ADLTs.

Some commenters suggested the new ADLT initial period should only begin once Medicare coverage is available for that particular test. Other commenters suggested that the CMS approval date for ADLT status should trigger the start date for the new ADLT initial period. For example, if a test is first performed on February 4, 2017, and CMS does not confer ADLT status until March 14, 2018, then it would be March 14, 2018, and not February 4, 2017, that would trigger the start of the new ADLT initial period.

Other commenters pointed out that CMS's proposed approach requires, before an ADLT can be paid at the actual list charge rate, that the laboratory has first sought and been granted ADLT status for its laboratory test and that Medicare coverage in the form of an initial claim determination or a local coverage policy has occurred. As such, some commenters believed we should clarify our proposed policy, while others suggested we should adopt a new policy, that when the agency says the initial period starts on the first day of the next calendar quarter following the first day on which the new ADLT is performed, that means the agency has already deemed the test to be an ADLT and Medicare coverage has been established.

Response: As discussed in the proposed rule (80 FR 59401), we proposed to start the new ADLT initial period on the first day of the first full calendar quarter following the first day on which a new ADLT is performed. We agree with commenters that our policy should try to ensure that a new ADLT is paid actual list charge during the new ADLT initial period.

We recognize that our proposed policy to tie the start of the new ADLT initial period to the date the test is first performed could mean new ADLTs will not be paid actual list charge. We understand that a Medicare coverage determination could be a lengthy process for the types of tests that are likely to qualify as ADLTs and that, consequently, a test may be available on the market and paid by private payors before Medicare covers and pays for it. Under our proposed policy, if the test has been available to private payors long before we grant ADLT status and provide Medicare coverage, the new ADLT initial period may have expired and the actual list charge rate would no longer apply.

We believe making the start of the new ADLT initial period contingent upon us making a Medicare Part B coverage determination for the test and approving the test for ADLT status will address stakeholder concerns that the new ADLT initial period might expire before Medicare makes payment at the actual list charge. We are revising our proposal accordingly. The new ADLT initial period will begin only when the test has been both covered under Medicare Part B and approved for ADLT status, regardless of the order in which the events take place. To ensure that both events have occurred, the date that triggers the date on which the new ADLT initial period begins will be the later of the two.

For example, if we approve a single laboratory's request for ADLT status on March 4, 2018, and a coverage determination for that test is made on August 10, 2018, the date that triggers the new ADLT initial period is August 10, 2018. The new ADLT initial period would begin October 1, 2018 because that is the first day of the first full calendar quarter following August 10, 2018. In another example, if a coverage determination for the test is made on April 6, 2018, and we approve a single laboratory's request for ADLT status on May 1, 2018, the date that triggers the new ADLT initial period would be May 1, 2018. The new ADLT initial period would begin July 1, 2018 because that is the first day of the first full calendar quarter following May 1, 2018.

To reflect this change to the start date of a new ADLT initial period, we are revising the definition of new ADLT initial period in § 414.502 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 or ADLT status is granted by us. In light of this change, we are also revising the data reporting requirements in § 414.504(c) to no longer require a laboratory seeking new ADLT status for its test to attest to the date the new ADLT is first performed as this information is no longer relevant for determining the start date of the new ADLT initial period.

Additionally we clarify here 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. As discussed in this final rule, 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. Therefore, the actual list charge amount could be known well before the start of the new ADLT initial period. For more discussion of the actual list charge, please refer to section II.H. in this final rule.

We also recognize 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 that case, we would use crosswalking and gapfilling methodologies to determine pricing for the new ADLT after the new ADLT initial period. We note that the use of crosswalking and gapfilling for determining pricing for ADLTs in such circumstances is consistent with how we will price other CDLTs for which no applicable information is reported in a data reporting period. We believe the requirement for laboratories to collect and report private payor rate data annually for ADLTs would mitigate most concerns about prolonged reliance on crosswalking and gapfilling to price ADLTs rather than private payor rates. We note that under the recoupment of payment for new ADLTs if actual list charge exceeds the market rate provision (section 1834A(d)(4) of the Act), the weighted median private payor rate determined during the new ADLT initial period is compared to the actual list charge. If no private payor rate data is reported during the new ADLT initial period, there would be no weighted median private payor rate to compare the actual list charge to and the recoupment provision would not be applicable. For more information on the recoupment of payment for new ADLTs, please refer to section II.H in this final rule.

Table 4 illustrates the final data collection and reporting period for a new ADLT, using the example above, 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 PERIOD 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 illustrates the final data collection and reporting periods for new ADLTs after the new ADLT initial period, using the example above, where the new ADLT initial period ends on March 31, 2019.

TABLE 5—EXAMPLE OF 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 year
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.

Comment: One commenter stated that, given that commercial payors' processes to price new codes and tests is lengthy, three quarters is not adequate time for a sufficient number of insurers to have paid for the test and contributed to the private payor data on which we will price the test. To address this concern, the commenter recommended that we extend the new ADLT initial period to one calendar year before reporting is required.

Response: Section 1834A(d)(1) of the Act requires a new ADLT initial period to be 3 quarters, and section 1834A(d)(2) of the Act requires applicable information for a new ADLT to be reported no later than the last day of the second quarter of the new ADLT initial period. As the statute is explicit about those time frames, we do not believe it would permit the new ADLT initial period to be a full calendar year or the first reporting to be after the new ADLT initial period is over. As discussed in response to a previous comment, if no private payor rate data are reported by the end of the second quarter of the new ADLT initial period, we will use crosswalking and gapfilling methodologies to determine pricing for the ADLT. We believe, however, the annual data collection and reporting requirement for ADLTs should alleviate concerns about the extended use of crosswalking and gapfilling, as opposed to private payor rates, to determine payment amounts for ADLTs.

E. Data Integrity

1. Penalties for Non-Reporting

Section 1834A(a)(9)(A) of the Act authorizes the Secretary to apply a CMP if the Secretary determines that an applicable laboratory has failed to report, or has made a misrepresentation or omission in reporting, information under section 1834A(a) of the Act for a CDLT. In these cases, the Secretary may apply a CMP in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission. Section 1834A(a)(9)(B) of the Act further provides that the provisions of section 1128A of the Act (other than sections (a) and (b)) shall apply to a CMP under this paragraph in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act. Section 1128A of the Act governs CMPs that apply to all federal health care programs. Thus the provisions of section 1128A of the Act (specifically sections 1128A(c) through 1128A(n) of the Act) apply to a CMP under section 1834A(a)(9) of the Act in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act. We noted that a similar provision is included in the law under section 1847A(d)(4) of the Act with regard to the reporting of average sales price by the manufacturer of a drug or biological. Given the similarity between sections 1834A(a)(9)(A) and 1847A(d)(4) of the Act, we proposed to adopt a provision in § 414.504(e) for implementing section 1834A(a)(9)(A) of the Act that is similar to § 414.806, the regulation governing drug manufacturers' reporting of Part B drug

prices under section 1847A(d)(4) of the Act. Following the final publication of this rule, we anticipate issuing guidance further clarifying these requirements.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Several commenters commented on the proposed CMPs of up to $10,000 per day per violation and said the amount should be reconsidered, particularly for community laboratories that cannot afford such penalties. The commenters also suggested that CMS only apply penalties in cases where there is evidence that a laboratory intentionally provided inaccurate or mistaken information.

Response: The statute authorizes CMPs of up to $10,000 per day per violation. However, in situations where our review reveals that the data submitted is incomplete or incorrect, we will work with the OIG to assess whether a CMP should be applied, and if so, the appropriate amount based on the specific circumstances. Although the statute authorizes CMPs of up to $10,000 per day per violation, we recognize that this is the maximum statutory amount, and not a minimum. The actual penalty imposed will be determined based on the facts and circumstances of each violation.

We note that this amount was recently amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Public Law 114–74, November 2, 2015) (the 2015 Act), which amends the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (Pub. L. 101–410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461 note 2(a)). The Inflation Adjustment Act required all agencies, including HHS, to adjust any CMPs within their jurisdiction by increasing the maximum CMP or the range of minimum and maximum CMPs, as applicable, for each CMP by the cost-of-living adjustment. The 2015 Act was enacted to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. Among other things, it revises the method of calculating inflation adjustments so that, instead of the significant rounding methodology applied under the Inflation Adjustment Act, penalty amounts are now simply rounded to the nearest $1. Accordingly, in applying the requirements of the Inflation Adjustment Act, as amended, to the penalty amounts specified in section 1834A(a)(9) of the Act, the Secretary may assess CMPs of up to $10,017 per day per violation beginning on the effective date of this rule. We have revised § 414.504(e) to reflect this statutory adjustment. The 2015 Act also requires agencies to publish annual adjustments not later than January 15 of every year after publication of the initial adjustment. Therefore, subsequent to this initial adjustment, CMP adjustments applicable to section 1834A of the Act will be updated annually through regulations published by the Secretary no later than January 15 of every year.

Comment: Several commenters requested clarification as to what constitutes an error that warrants a penalty, and stated that CMS should not apply any penalties or sanctions for reporting errors until an appeals process is outlined. Some commenters stated that CMS indicated in the proposed rule that full implementation of the new CLFS regulations will take between 5 and 6 years, and suggested that no penalties be assessed during this time.

Response: As previously mentioned, following the publication of this final rule, we will issue additional guidance on the assessment of CMPs, including what would constitute a failure to report or a misrepresentation or omission in reporting. We also note that we do not intend to assess CMPs for minor errors. The actual penalty imposed will be determined based on the facts and circumstances of each violation. While full implementation of the new CLFS regulations will take several years, it is critical that reporting entities provide accurate and complete information at the outset so that accurate prices can be set, and while we do not expect that CMPs will be assessed frequently, we believe the ability to assess CMPs on reporting entities when appropriate is consistent with our statutory authority. Section 1834A(a)(9)(B) of the Act further provides that the provisions of section 1128A of the Act (other than sections (a) and (b)) shall apply to a CMP under this paragraph in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act.

Comment: A commenter stated that the economics and other characteristics of the laboratory industry differ greatly from the pharmaceutical industry making the comparison to Part B drugs inapplicable.

Response: We agree there are important differences between the pharmaceutical industry and the laboratory industry, but believe the general approach taken for the application of CMPs for violations in reporting drug prices is an appropriate model to consider when we develop guidance on the application of CMPs for violations in reporting of applicable information.

Comment: A commenter stated that CMPs can be an effective tool for encouraging data reporting and ensuring compliance with the PAMA reporting obligations but that there will be significant confusion within the laboratory community initially. The commenter requested that CMS not impose CMPs during the initial cycle on any laboratory that has shown a good faith effort to comply with the reporting requirements, and that CMS should notify applicable laboratories of their reporting obligations to ensure compliant reporting and to reduce the likelihood of penalties.

Response: We appreciate the commenter's understanding of the important role of CMPs in ensuring accurate and complete data reporting and acknowledge the commenter's concerns regarding the provision of data during the initial reporting period. We are uncertain as to what the commenter means by ''any laboratory that has shown a good faith effort to comply with the reporting requirements'' As we have noted previously, we do not intend to assess CMPs for minor errors, and will provide additional information in subregulatory guidance to facilitate compliant reporting and to reduce the likelihood of penalties. Additionally, we are clarifying in § 414.504(e) that the CMPs will be assessed at the reporting entity level, not at the applicable laboratory level, to ensure consistency with the data reporting and certification requirements that the reporting entity is obligated to follow, as addressed in the other paragraphs in § 414.504.

Comment: Some commenters stated that smaller laboratories without sufficient administrative staff face challenges in reporting as compared to larger, well-resourced laboratories. These commenters suggested that the size of the penalty should correspond to the size of the laboratory, so that laboratories with limited resources would not be forced to close as a result of such penalties.

Response: We will consider all relevant information when determining the amount of a CMP, and we will work with the OIG to ensure that any penalties assessed are fairly applied. The purpose of PAMA is to collect complete and accurate data in order to set payment rates, not to force a laboratory to close as a result of a CMP assessment.

Comment: Some commenters were concerned that the period to understand and comply with the data requirements is too short and could compromise the integrity of the data submitted.

Response: In section II.D of this final rule, we discuss our final data collection and reporting process, which is changed from our proposal in the proposed rule. Under the process we are adopting in this final rule, applicable laboratories will have a 6-month data collection period, followed by a 6-month period between the end of the data collection period and the beginning of the data reporting period to allow applicable laboratories time to ensure the accuracy of their data, followed by a 3-month data reporting period during which reporting entities will report applicable information to us. We believe this process will provide applicable laboratories adequate time to understand and prepare for the submission of the required data.

Comment: Some commenters noted that accidental errors are inevitable with a new, first-of-its-kind, untested laboratory price reporting system, and the associated fines are significant. These commenters also opined that the new reporting requirements will require significant changes for the clinical laboratory community to undertake with no funding provided to make those changes, and that implementation of this law is being fast-tracked, which will lead to mistakes and unexpected problems.

Response: As discussed in section II.D.3 of this final rule, we are moving the implementation date of section 1834A of the Act to January 1, 2018. We expect applicable laboratories will have sufficient time to review their data for accuracy and completeness during the 6-month time period we are affording between the end of the data collection period and the beginning of the data reporting period. We recognize that there is a cost associated with the development and submission of data under section 1834A of the Act, but we believe this data submission process is an essential mechanism to establish fair and accurate Medicare payment rates for CDLTs. We are proceeding with implementation of the new reporting requirements in accordance with the statutory requirements, notwithstanding the new implementation date of January 1, 2018.

2. Data Certification

Section 1834A(a)(7) of the Act requires that an officer of each laboratory must certify the accuracy and completeness of the reported information required by section 1834A(a) of the Act. We proposed to implement this provision by requiring in § 414.504(d) 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 provided is accurate, complete, and truthful, and meets all the reporting parameters. We stated that we would specify the processes for certification in subregulatory guidance prior to January 1, 2016.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: A few commenters objected to our plan to specify the processes for certification in subregulatory guidance prior to January 1, 2016, stating that some of these process issues need to be resolved in the final rule before subregulatory guidance is issued. Others have asked that the subregulatory guidance be issued as soon as possible.

Response: We will issue subregulatory guidance specifying the certification process for the submission of applicable information following publication of this final rule. As discussed in section II.D.3 of this final rule, we are moving the implementation date of the revised CLFS to January 1, 2018, so we now expect to issue the subregulatory guidance prior to January 1, 2018.

Comment: Some commenters requested that CMS create a certification form for applicable laboratories that states that the information and statements submitted are accurate and complete to the best of the laboratory's knowledge and the submission is made in good faith.

Response: We appreciate the commenters' suggestion and will take it into consideration as we develop subregulatory guidance for the certification process following the publication of this final rule.

Comment: Some commenters stated that most laboratory Presidents, CEOs, and CFOs are not personally familiar with the volume and private payor rates for each laboratory test their labs offer, and they should not be required to certify the accuracy of the data submitted. The commenter suggested that a laboratory officer should be responsible for certifying that the data submitted is accurate to the best of his or her knowledge.

Response: We agree with the commenter and in accordance with the changes to the data reporting requirements in this final rule, we have revised § 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

Section 1834A(a)(10) of the Act addresses the confidentiality of the information disclosed by a laboratory under section 1834A(a) of the Act. Specifically, the paragraph provides that, notwithstanding any other provision of law, information disclosed by a laboratory under section 1834A(a) of the Act is confidential and must not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identity of a specific payor or laboratory, or prices charged or payments made to any such laboratory, except as follows:

- As the Secretary determines to be necessary to carry out section 1834A of the Act;
- To permit the Comptroller General to review the information provided;
- To permit the Director of the Congressional Budget Office (CBO) to review the information provided; and
- To permit MedPAC to review the information provided.

These confidentiality provisions apply to information disclosed by a laboratory under section 1834A(a) of the Act, the paragraph that addresses reporting of applicable information for purposes of establishing CLFS rates, and we interpreted these protections as applying to the applicable information that applicable laboratories report to CMS under proposed § 414.504(a). We did not interpret section 1834A(a)(10) of the Act as applying to other information laboratories may submit to CMS that does not constitute applicable information, for example, information regarding an applicable laboratory's business structure, such as its associated NPI entities, or information submitted in connection with an application for ADLT status under section 1834A(d) of the Act, including evidence of a laboratory's empirically derived algorithms and how the test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

In section II.H of this final rule, we discuss in more detail how we will use the applicable information reported under § 414.504 to set CLFS payment rates, and intend to make available to the public a list of test codes and the CLFS payment rates associated with those codes, which is the same CLFS information we currently make available. This information would not reveal the identity of a specific payor or laboratory, or prices charged or

payments made to a specific laboratory (except as noted below), and thus, we believed continuing to publish this limited information would allow us to comply with section 1834A(a)(10) of the Act while continuing to provide necessary information to the public on CLFS payment amounts.

As noted above, section 1834A(a)(10) of the Act lists four instances when the prohibition on disclosing information reported by laboratories under section 1834A(a) of the Act would not apply, the first being when the Secretary determines disclosure is necessary to carry out section 1834A of the Act. We believe certain disclosures will be necessary for us to administer and enforce the new Medicare payment system for CDLTs. For example, it may be necessary to disclose to the HHS OIG confidential data needed to conduct an audit, evaluation, or investigation or to assess a CMP, or to disclose to other law enforcement entities such as the Department of Justice confidential data needed to conduct law enforcement activities. Therefore, we proposed to add those entities to the list of entities in § 414.504(f) to which we may disclose applicable information that is otherwise confidential. Additionally, there may be other circumstances that require the Secretary to disclose confidential information regarding the identity of a specific laboratory or private payor. If we determine that it is necessary to disclose confidential information for other circumstances, we would notify the public of the reasons through a **Federal Register** announcement, if deemed necessary, or via a CMS Web site prior to making such disclosure.

Also, we believed that codes and associated CLFS payment rates published for ADLTs may indirectly disclose the identity of the specific laboratories selling those tests, and, for new ADLTs, payments made to those laboratories. As explained in this section, ADLTs are offered and furnished only by a single laboratory. Thus, in the proposed rule, we believed publishing the test code and associated CLFS payment rate for an ADLT would indirectly reveal the identity of the laboratory because only a single laboratory would be offering and furnishing that test. Moreover, because Medicare will pay actual list charge for a new ADLT during the new ADLT initial period, publishing the test code and associated CLFS rate for a new ADLT would, we believe, reveal the payments made to the laboratory offering and furnishing that test. We believe section 1834A(a)(10)(A) of the Act authorizes us to publish the test codes and associated CLFS payment rates for ADLTs and we do not believe we can do so without indirectly revealing ADLT laboratory identities and payments made to those laboratories. However, because the actual list charge for a new ADLT would already be publicly available, we do not believe laboratories will be harmed by our publishing the CLFS rates for new ADLTs. We indicated that we would not publish information that directly discloses a laboratory's identity, but we could not prevent the public from associating CLFS payment information for an ADLT with the single laboratory offering and furnishing the test.

Section 1834A(a)(10) of the Act also prohibits a Medicare contractor from disclosing information under section 1834A(a) of the Act in a form that reveals the identity of a specific payor or laboratory, or prices charged or payments made to any such laboratory. We stated in the proposed rule that we did not expect this prohibition to be problematic as applicable laboratories would be reporting applicable information to CMS and not the MACs. When a MAC sets rates under our new policies, we expect the MAC will follow its current practice for pricing when developing a local payment rate for an item or service that does not have a national payment rate, that is, it would only disclose pricing information to the extent necessary to process and pay a claim.

We proposed to implement the confidentiality requirements of section 1834A(a)(10) of the Act in § 414.504(f).

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Many commenters agreed with the confidentiality provisions outlined in the proposed rule, but expressed concern regarding disclosure of certain information laboratories would be required to report under section 1834A of the Act. For example, commenters were concerned that information such as payor names could be revealed to the public. One commenter suggested that payor names are not necessary to carry out the requirements of section 1834A, and that it is also unnecessary for the Comptroller General, Director of the Congressional Budget Office, and MedPAC to review information that will be reported by laboratories. The commenter requested that CMS ensure the rates paid by specific payors are not easy to discern.

A few commenters requested that CMS protect all reported information from public disclosure. One commenter requested assurance that disclosures made as the Secretary determines to be necessary to carry out the requirements of the law are made judiciously and without revealing more information than is truly necessary.

A commenter indicated that the form and manner specified for reporting applicable information should ensure that private payor names are not reported. Along those same lines, another commenter suggested that language be added to § 414.504(b) to explicitly state that private payor names are to be omitted from or otherwise obscured in all reporting materials. The commenter opined that including this instructive language solely in separate subregulatory guidance materials would be insufficient and that it needs to be included in the regulation to make the requirements clear, eliminate any uncertainty regarding confidentiality for clinical laboratories subject to the new law, and protect price competition in the marketplace.

Response: We appreciate the commenters' concerns and suggestions regarding the confidentiality and data reporting provisions. As discussed above, CMS and the MACs will not publicly disclose applicable information reported under section 1834A(a) of the Act in a form that would reveal the identity of a specific payor or laboratory, or prices charged or payments made to a specific laboratory. While the commenter is correct that we can fulfill our obligations under section 1834A without disclosing the information to the Comptroller General, the Director of CBO, and MedPAC, the statute specifically provides for disclosure to those entities to permit them to review the information, if needed to carry out their responsibilities. Section 1834A(a)(10)(A) of the Act also authorizes us to disclose the information as we determine necessary to implement section 1834A(a) of the Act, which we proposed to use for such activities as oversight and enforcement in conjunction with the HHS OIG or the Department of Justice. We assure commenters that we will limit disclosure of information for the purpose of conducting such activities to only what is truly necessary.

Although we appreciate the commenter's suggestion for adding language to the regulations to explicitly state that private payor identities are not to be revealed in reporting applicable information, we do not believe it is necessary. Section 1834A(a)(11) of the Act specifies that a payor shall not be identified on applicable information. In our data reporting requirements at

§ 414.504(b), we require that applicable information must be reported in the form and manner specified by us. We do not agree it is necessary to include in the regulations the specific form and manner for submitting applicable information. As we discussed in section II.D.2 of this final rule, we will only require the minimum information necessary to be reported to enable us to set CLFS payment rates. Generally, in reporting applicable information, we expect laboratories to report the specific HCPCS code associated with each laboratory test, the private payor rate or rates associated with the HCPCS code, and the volume of laboratory tests performed by the laboratory at each private payor rate. We will not permit individual claims to be reported because claims include more information than we need to set payment rates and they contain personally identifiable information. We also will not permit private payor names to be reported because section 1834A(a)(11) of the Act prohibits a payor from being identified on information reported. Our guidance will reflect these instructions.

Comment: Many commenters expressed concern that our proposal to use the existing annual update process, in which we publish only a list of test codes and the CLFS payment rates associated with those codes, would be insufficient information for the public to review the new payment rates established under section 1834A of the Act. The commenters stated, with a new reporting system of this magnitude and complexity that relies on laboratories providing correct and uniform information, it is essential for CMS to also explain how it derived the new payment rates. Rather than simply announcing payment amounts, the commenters suggested CMS allow for notice and comment rulemaking to provide an opportunity for the agency to outline what data it received, from how many laboratories and the type(s) of laboratories that submitted data (for example, physician office laboratories, independent laboratories), the variances in the data, and how CMS reconciled any variances. Commenters suggested that, for laboratories to appropriately comment on the new CLFS rates under section 1834A, they will need to be able to review more data than just the rates.

Response: In section II.H. of this final rule, we provide a comprehensive explanation of how the payment rates will be set under section 1834A of the Act, and we believe that is sufficient for the laboratory industry to understand how the rates we will announce are established.

As indicated above in this section, we intend to make available to the public a list of test codes and the CLFS payment rates (that is, the weighted median of private payor rates) associated with those codes, which is the same CLFS information we currently make available to the public annually in November. However, under the new process, we expect to release this file earlier than November so the public will have more opportunity to review and comment on the payment rates before they are implemented. In addition, to address commenters' concerns about data transparency, we also intend to make available to the public, a file that includes summary or aggregate-level private payor rate and volume data for each test code such as, the unweighted median private payor rate, the range of private payor rates, the total, median and mean volume, and the number of laboratories reporting. Such information will also be released to the public before the final rates are published to better enable the public to comment on the general accuracy of the reported data. In providing this information, we will not release any information that identifies a payor or a laboratory.

In addition to publishing the aggregate-level private payor rate and volume data, we are also exploring whether we can make available a file of the raw data, that is, the actual, un-aggregated data that is reported as applicable information for an applicable laboratory. We believe this process could provide even more transparency for the public to review and comment on the new CLFS payment rates before they are made effective. Details of this process, if we decide we can release the raw data, would be provided in subregulatory guidance.

Although we noted in the proposed rule that we cannot prevent the public from associating applicable information for an ADLT with the single laboratory offering and furnishing the test (80 FR 59402), we have given further consideration to how we may protect the identity of such laboratories from public disclosure. Although we believe we could release the applicable information for ADLTs in raw or aggregate form under the authority of section 1834A(a)(10)(A) of the Act, we recognize and appreciate that commenters are especially concerned about confidentiality and risk of disclosure of propriety information. Therefore, we have decided, for tests we consider to be uncommon or that we know to be provided only by a single laboratory (such as for new ADLTs), we will not release applicable information in aggregate form, or raw form if we decide we can release the raw data. However, we will provide the HCPCS code and CLFS rate associated with those tests consistent with our current annual publication of the CLFS file. We consider a test to be ''uncommon'' if it is offered or furnished by only a few laboratories or if it is paid by only a few private payors. We will clarify further what we mean by ''a few laboratories'' and ''a few private payors'' after we evaluate the private payor data we receive in the first data reporting period of January 1, 2017 through March 31, 2017, and we will publish that clarification along with the public files we discussed above in this section.

Comment: A few commenters believed proprietary algorithms that are submitted as part of an ADLT application should be protected from public disclosure. To that end, they requested we make proprietary and confidential information submitted for purposes of requesting ADLT status exempt from disclosure under the Freedom of Information Act (FOIA) Exemption 4. These commenters indicated that the proprietary information should be identified as a ''trade secret'' at the time of the ADLT application and thus should be protected from disclosure under FOIA.

Response: As discussed in section III.C of this final rule, we do not have the statutory authority to automatically exempt confidential information submitted as part of an ADLT application from public disclosure. The statute provides for the confidentiality of applicable information disclosed by a laboratory under section 1834A(a) of the Act, but section 1834A(d) of the Act, which relates to the requirements a test must meet to be an ADLT, does not.

FOIA includes an exemption for trade secrets and commercial and financial information obtained from a person that is privileged or confidential. While we do not have the authority to provide automatic protection from public disclosure under FOIA Exemption 4, if an applicant submits an ADLT application that includes trade secrets or certain commercial or financial information, specified above, it is possible the information could be withheld from public disclosure under the FOIA exemption. An applicant that wishes to protect the information submitted in an ADLT application would mark it proprietary and confidential, and substantiate that statement by expressly claiming substantial competitive harm if the information is disclosed, and demonstrating 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.

Comment: One commenter reasoned that the submission of evidence relating to an empirically derived algorithm is voluntary because laboratories could apply for ADLT status under criterion B by submitting validation of premarket clearance or approval from the FDA. Therefore, the commenter believes the information submitted as part of an ADLT application under criterion A is protected from public disclosure under FOIA Exemption 4 because the voluntarily provided information should be kept confidential if it is of the kind the company would not customarily release to the public.

Response: An ADLT applicant may request ADLT status for a laboratory test based on criterion A or criterion B. If an applicant chooses to submit a request for ADLT status under criterion A, the applicant will be required to submit evidence of the empirically derived algorithm and show how a test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. Information voluntarily submitted to the government may, in some circumstance, be protected from disclosure by FOIA in accordance with the goal of encouraging the cooperation of persons that may have information that would be useful to the government. The submission of information to support an ADLT application is not voluntary in that respect, and the protections from FOIA regarding voluntary information, as cited by the commenter, do not apply to information submitted by an applicant requesting ADLT status for a laboratory test under criterion A.

G. Coding for Certain Clinical Diagnostic Laboratory Tests (CDLTs) on the CLFS

Section 1834A(e) of the Act includes coding requirements for certain new and existing ADLTs and laboratory tests that are cleared or approved by the FDA. In this section, we describe our current coding system for the CLFS and how we proposed to utilize aspects of this system to implement the coding provisions in section 1834A(e) of the Act.

1. Background

Currently, new tests on the CLFS receive HCPCS level I codes (CPT) from the American Medical Association (AMA). The CPT is a uniform coding system consisting of descriptive terms and codes that are used primarily to identify medical services and procedures furnished by physicians, suppliers, and other health care professionals. Decisions regarding the addition, deletion, or revision of CPT codes are made by the AMA, and published and updated annually by the AMA. Level II of the HCPCS is a standardized coding system used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Because Medicare and other insurers cover a variety of services, supplies, and equipment that are not identified by CPT codes, the HCPCS level II codes were established for submitting claims for these items.

Within CMS, the CMS HCPCS Workgroup, which is comprised of representatives of major components of CMS and consultants from pertinent Federal agencies, is responsible for all revisions, deletions, and addition to the HCPCS level II codes. As part of its deliberations, the CMS HCPCS Workgroup may develop temporary and permanent national alpha-numeric HCPCS level II codes. Permanent HCPCS level II codes are established and updated annually, whereas temporary HCPCS level II codes are established and updated on a quarterly basis. Temporary codes are useful for meeting, in a short time frame, the national program operational needs of a particular insurer that are not addressed by an already existing national code. For example, Medicare may need additional codes before the next annual HCPCS update to implement newly issued coverage policies or legislative requirements.

Temporary HCPCS level II codes do not have established expiration dates; however, a temporary code may be replaced by a CPT code, or the CMS HCPCS Workgroup may decide to replace a temporary code with a permanent HCPCS level II code. For example, a laboratory may request a code for a test in the middle of a year. Because permanent codes are assigned only once a year, the CMS HCPCS Workgroup may assign the laboratory test a temporary HCPCS level II code. The temporary code may be used indefinitely or until a permanent code is assigned to the test. Whenever the CMS HCPCS Workgroup establishes a permanent code to replace a temporary code, the temporary code is cross-referenced to the new permanent code and removed.

''G codes'' are temporary HCPCS level II codes that we use to identify professional health care procedures and services, including laboratory tests, that would otherwise be identified by a CPT code, but for which there is no CPT code. We have used G codes for laboratory tests that do not have CPT codes but for which we make payment, or in situations where we want to treat the codes differently from the CPT code descriptor for Medicare payment purposes.

2. Coding under PAMA

Section 1834A(e) of the Act includes three provisions that relate to coding: (a) Temporary codes for certain new tests; (b) coding for existing tests; and (c) establishment of unique identifiers for certain tests. The effect of section 1834A(e) of the Act is to require the Secretary to establish codes, whereas prior to the enactment of PAMA, the Secretary had discretion to establish codes, but was not required to do so. Before we discussed each of the three provisions in the proposed rule, we addressed several specific references in the statute that we believed needed clarification.

In the three coding provisions, the statute requires us to ''adopt,'' ''assign,'' and ''establish'' codes or identifiers. We believe those terms to be interchangeable. There is no practical difference between them for purposes of CMS's obligation under section 1834A(e) of the Act, which is, essentially, to ensure that certain laboratory tests can be identified by a HCPCS code, or in the case of section 1834A(e)(3) of the Act, a unique identifier. The statute also refers to ''new laboratory tests'' and ''existing clinical diagnostic laboratory test[s]'' in sections 1834A(e)(1)(A) and (2), respectively. We believe new laboratory tests here refers to CDLTs (that are cleared or approved by the FDA) paid under the CLFS on or after January 1, 2017, and existing CDLTs refers to CDLTs (that are cleared or approved by the FDA) paid under the CLFS prior to that date.

a. Temporary Codes for Certain New Tests

Section 1834A(e)(1)(A) of the Act requires the Secretary to adopt temporary HCPCS codes to identify new ADLTs and new laboratory tests that are cleared or approved by the FDA. As discussed previously, we proposed a definition for new ADLTs, and we also discussed what it means for a laboratory test to be cleared or approved by the FDA. We applied those interpretations in this section. We understood the statute to be requiring us to adopt temporary HCPCS level II codes for these two types of laboratory tests if they have not already been assigned a HCPCS code. Therefore, we stated we would use the existing HCPCS coding

process for these tests. This means, if a new ADLT or a new CDLT that is FDA-cleared or -approved is not already assigned a CPT code or HCPCS level II code, we would assign a G code to the test. The statute further directs that the temporary code be effective for up to 2 years until a permanent HCPCS code is established, although the statute permits the Secretary to extend the length of time as appropriate. Therefore, we indicated that any G code that we adopt under this provision would be effective for up to 2 years, unless we believed it appropriate to continue to use the G code. For instance, we may create a G code to describe a test for prostate specific antigen (PSA) that may be covered by Medicare under sections 1861(s)(2)(P) and 1861(oo)(2)(B) of the Act as a prostate cancer screening test. At the end of 2 years, if the AMA has not created a CPT code to describe that test but Medicare continues to have a need to pay for the test described by the G code, we would continue to use the G code.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Many commenters recommended that, whenever available, CMS utilize the existing HCPCS codes created and assigned by the CPT Editorial Panel for new tests on the CLFS. Commenters explained that private payors often do not recognize G codes assigned by Medicare and that the use of G codes may confuse the billing process and collection of private payor data should private payors use different codes for the same tests. Some commenters stated that a two-step coding process (that is, a temporary G code first, then a permanent CPT code) for new ADLTs would be unnecessarily burdensome for both CMS and clinical laboratories. Commenters also suggested that a quarterly process for assigning permanent codes to ADLTs would be more efficient and lead to more accurate coding and data reporting than the G code process outlined by CMS in the proposed rule.

Response: We understand the commenters' concerns and are clarifying in this final rule that we will use existing HCPCS level I codes created by the CPT Editorial Panel whenever possible. As discussed above in this section, decisions regarding the addition, deletion, or revision of CPT codes are currently made annually by the AMA. CMS does not have authority to change the AMA's annual process to a quarterly process. As has been our standard practice, we expect to use G codes only when CPT codes are unavailable or do not meet our coding needs. In the event that we will need to assign a new G code to an ADLT, or to a CDLT that is cleared or approved by the FDA, we will make such assignments on a quarterly basis, consistent with our current process for updating HCPCS codes. Any temporary HCPCS code will be considered for replacement by a permanent CPT code when it is made available by the AMA, and if it satisfies our coding and payment needs, as part as the annual laboratory public meeting process discussed in section I.B.1 of this final rule.

b. Coding and Publication of Payment Rates for Existing Tests

Section 1834A(e)(2) of the Act stipulates that not later than January 1, 2016, for each existing ADLT and each existing CDLT that is cleared or approved by the FDA for which payment is made under Medicare Part B as of PAMA's enactment date (April 1, 2014), if such test has not already been assigned a unique HCPCS code, the Secretary shall (1) assign a unique HCPCS code for the test and (2) publicly report the payment rate for the test.

As with the requirement for us to adopt codes for certain new tests under section 1834A(e)(1) of the Act, we discussed in the proposed rule that we believed our existing coding process is consistent with the requirements of section 1834A(e)(2) of the Act. Accordingly, we stated that we would use the existing HCPCS coding process for these tests, meaning, if an existing ADLT or existing CDLT is not already assigned a CPT code or a HCPCS level II code, we would assign a G code to the test.

One aspect of section 1834A(e)(2) of the Act (applying to existing tests) that is different than section 1834A(e)(1) of the Act (applying to certain new tests) is the requirement for us to assign a ''unique'' HCPCS code. We explained in the proposed rule that we understand a unique HCPCS code to describe only a single test. An ADLT is a single test, so each existing ADLT would be assigned its own G code. However, it is possible that one HCPCS code may be used to describe more than one existing CDLT that is cleared or approved by the FDA. For instance, explained in the proposed rule, we understand there are different versions of laboratory tests for the Kirsten rat sarcoma viral oncogene homolog (KRAS)—one version that is FDA-approved and others that are not FDA-cleared or -approved. Currently, the same HCPCS code is used for both the FDA-approved laboratory test for KRAS and the non-FDA-cleared or -approved versions of the test. Thus, the current HCPCS code is not unique in describing only the FDA-approved version of the KRAS test. Under section 1834A(e)(2) of the Act, we are required to ensure that FDA-cleared or -approved versions of the KRAS test are assigned their own unique codes.

As we discussed in the proposed rule, section 1834A(e)(2)(B) of the Act requires us to publicly report the payment rate for existing ADLTs or tests that are cleared or approved by the FDA by January 1, 2016. We noted that we did not meet the deadline for this requirement as we would have established by January 1, 2016 the final definition of an ADLT, an ADLT application process, and a process for identifying FDA-cleared or -approved tests. In section II.D. of this final rule we stated, in response to comments, that we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. Consistent with this change in implementing the new CLFS payment rates, we believe it is appropriate to adopt a corresponding change in assigning and publicly reporting the payment rates for existing ADLTs and tests that are cleared or approved by the FDA. Therefore, by January 1, 2017, we will assign and publish payment rates for existing ADLTs and tests cleared or approved by the FDA. We will publish the ADLT application process and the process for specifying that a test is cleared or approved by the FDA in subregulatory guidance.

It is possible there are existing ADLTs or CDLTs cleared or approved by the FDA that are currently being priced under our existing regulations using crosswalking or gapfilling. For instance, some tests are currently being priced using gapfilling (see *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2015-CLFS-Codes-Final-Determinations.pdf*). If any of the tests that are currently being priced using gapfilling fall within the category of existing laboratory tests under section 1834A(e)(2) of the Act, we will be able to report the payment rate for them by January 1, 2017. To fulfill the requirement to publicly report payment rates, we will include the codes and payment amounts on the electronic CLFS payment file that we will make available on the CMS Web site prior to January 1, 2017. We are currently considering how we would present the information. We expect to provide a separate field with a special identifier indicating when a HCPCS code uniquely describes an existing

laboratory test, although we may separately identify those codes that uniquely identify an existing test in separate documentation describing the file.

Comment: A few commenters recommended that we not assign unique codes to tests if they already have a code that is being billed to Medicare. The commenters advised against assigning unique codes to every FDA-cleared or -approved test as this could result in duplicative coding efforts. Thus, commenters believed a CDLT with FDA clearance or approval should not receive a unique HCPCS code. One commenter stated that there is no clinical or economic rationale for us to use our current coding process to differentiate between FDA-cleared or -approved tests and non-FDA-cleared or -approved tests. The commenter explained there may be unintended consequences of generating these codes ahead of any further actions from the FDA with regard to the oversight of laboratory tests. In addition, the commenter suggested that it is not apparent from the statute that an FDA-cleared or -approved CDLT should not share its code with a clinically equivalent non-FDA-cleared or -approved CDLT, nor that doing so would be inconsistent with the requirements under section 1834A(e) of the Act. Some commenters also suggested that if we do assign unique codes for FDA-cleared or -approved tests, then we should establish the temporary HCPCS code through public notice and comment rulemaking to allow for transparency and multi-stakeholder input. A few commenters recommended that, rather than doing so automatically, we should assign a unique HCPCS code for an ADLT or an FDA-cleared or -approved test only when a laboratory or manufacturer requests a unique code.

Response: We understand the commenters' concerns regarding assigning unique codes to an FDA-cleared or -approved version of a test. However, as we discussed in this section, the statute requires the Secretary to adopt a unique HCPCS code for each existing ADLT and each new CDLT that is cleared or approved by the FDA if such tests are not already assigned a unique HCPCS code, and we view ''unique'' in this context to mean a HCPCS code that describes only a single test. We agree that our assignment of such codes should be done with transparency and multi-stakeholder input. As these codes would be new for the CLFS, they would be subject to the CLFS annual public meeting process, which provides for a public review and comment period for new and reconsidered tests (for more detail on this process, see section I.B.1 of this final rule). We believe our current CLFS public process, which is required to continue under section 1834A(e)(3) of the Act, will sufficiently address the public's needs for transparency and input in the assignment of unique codes for these tests. Therefore, we do not agree that the assignment of HCPCS codes for this purpose should be subject to notice and comment rulemaking.

To alleviate commenters' concerns that we will automatically assign a unique HCPCS code for an ADLT or an FDA-cleared or -approved test, we note that laboratories must first indicate to the agency that its test requires a unique code. We may not be aware of existing ADLTs or CLDTs that are cleared or approved by the FDA that do not already have a unique HCPCS code. Details regarding how laboratories must notify us will be specified in subregulatory guidance.

c. Establishing Unique Identifiers for Certain Tests

Section 1834A(e)(3) of the Act requires the establishment of a unique identifier for certain tests. Specifically, section 1834A(e)(3) of the Act provides that, for purposes of tracking and monitoring, if a laboratory or a manufacturer requests a unique identifier for an ADLT or a laboratory test that is cleared or approved by the FDA, the Secretary shall use a means to uniquely track such test through a mechanism such as a HCPCS code or modifier. Section 1834A(e)(3) of the Act applies only to those laboratory tests that are addressed by sections 1834A(e)(1) and (2) of the Act, that is, new and existing ADLTs and new and existing CDLTs that are cleared or approved by the FDA.

The statute does not define ''tracking and monitoring.'' However, in the context of a health insurance program like Medicare, tracking and monitoring would typically be associated with enabling or facilitating the obtaining of information included on a Medicare claim for payment to observe such factors as: Overall utilization of a given service; regional utilization of the service; where a service was provided (for example, office, laboratory, hospital); who is billing for the service (for example, physician, laboratory, other supplier); which beneficiary received the service; and characteristics of the beneficiary receiving the service (for example, male/female, age, diagnosis). As the HCPCS code is the fundamental variable used to identify an item or service, and can serve as the means to uniquely track and monitor many various aspects of a laboratory test, we believed the requirements of this section would be met by the existing HCPCS coding process. Therefore, we proposed to implement section 1834A(e)(3) of the Act using our current HCPCS coding system, which we are finalizing in this final rule. If a laboratory or manufacturer specifically requests a unique identifier for tracking and monitoring an ADLT or an FDA-cleared or -approved CDLT, we will assign it a unique HCPCS code if it does not already have one.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: A few commenters recommended that we implement a more granular coding structure than the HCPCS coding processes for tests on the CLFS. Specifically, they suggested we use the McKesson Z codes which, they explained, provide granularity to the level of the specific laboratory that furnishes the test. The commenters mentioned that our contractor for the MolDx program and several private payors already utilize Z codes and suggest they can be adapted to our needs for assigning unique identifiers for certain tests, as required under section 1834A(e)(3) of the Act.

Response: We believe our current HCPCS coding processes will sufficiently meet our coding needs under section 1834A(e)(3) of the Act. We also note that, as of this final rule, the McKesson Z codes are not a HIPAA-compliant code set; HCPCS and CPT–4 are the current medical data code set standards adopted for use in health care claims transactions for physician and other health care services, such as CDLTs (see 42 CFR 162.1000 and 162.1002).

Comment: One commenter requested to be allowed to assist us in the ADLT application process and to be involved with the coding of new ADLTs.

Response: We appreciate the commenter's offer of assistance in the matter of designating a test as an ADLT and coding new ADLTs. We plan to consider recommendations of the CDLT Advisory Panel (see the discussion of the Panel in section II.J.1. of this final rule) as part of the process for determining ADLT status and assigning an ADLT a unique code. Meetings of the Panel are open to the public and input from the public is welcome. Announcements of the Panel meetings are published in the **Federal Register** and meeting agendas are posted on CMS's CLFS Web site at: *https://www.cms.gov/Regulations-and-Guidance/*

Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

H. Payment Methodology

1. Calculation of Weighted Median

Section 1834A(b) of the Act establishes a new methodology for determining Medicare payment amounts for CDLTs on the CLFS. Section 1834A(b)(1)(A) of the Act establishes the general requirement that the Medicare payment amount for a CDLT furnished on or after January 1, 2017, shall be equal to the weighted median determined for the test for the most recent data collection period. Section 1834A(b)(2) of the Act requires the Secretary to calculate a weighted median for each laboratory test for which information is reported for the data collection period by arraying the distribution of all private payor rates reported for the period for each test weighted by volume for each private payor and each laboratory. As discussed later in this section, the statute includes special payment requirements for new ADLTs and new CDLTs that are not ADLTs.

To illustrate how we proposed to calculate the weighted median for CDLTs, we provided examples of several different scenarios in the proposed rule (80 FR 59404 through 59406). These examples showed how we planned to determine the weighted median and were not exhaustive of every possible pricing scenario. In the first example, as depicted in Table 6, we supposed that the following private payor rate and volume information for three different CDLTs was reported for applicable laboratories.

TABLE 6—EXAMPLE OF THE CALCULATION OF THE WEIGHTED MEDIAN

	Test 1		Test 2		Test 3	
	Private payor rate	Volume	Private payor rate	Volume	Private payor rate	Volume
Lab. A	$5.00	1,000	$25.00	500	$40.00	750
Lab. B	9.00	1,100	20.00	2,000	41.00	700
Lab. C	6.00	900	23.50	1,000	50.00	500
Lab. D	2.50	5,000	18.00	4,000	39.00	750
Lab. E	4.00	3,000	30.00	100	45.00	850

In this example, there are five different private payor rates for each test. Table 6 is shown again as Table 7 with each test arrayed by order of the lowest to highest private payor rate, with each private payor rate appearing one time only so as to not reflect volume weighting.

TABLE 7—EXAMPLE OF THE CALCULATION OF THE UNWEIGHTED MEDIAN

	Test 1	Test 2	Test 3
	Private payor rate	Private payor rate	Private payor rate
Lowest (1)	$2.50	$18.00	$39.00
Next in Sequence (2)	4.00	20.00	40.00
Next in Sequence (3)	5.00	23.50	41.00
Next in Sequence (4)	6.00	25.00	45.00
Highest (5)	9.00	30.00	50.00

With five different private payor rates for each test, the unweighted median is the middle value or the third line in the table where there are an equal number of private payor rates listed above and below the third line in the table. The *unweighted* median private payor rate for each test would be:

- Test 1 = $5.00
- Test 2 = $23.50
- Test 3 = $41.00

These results are obtained by arraying the distribution of all private payor rates reported for the period for each test without regard to the volume reported for each private payor and each laboratory. To obtain the weighted median, we would do a similar array to the one in Table 7 except we would list each distinct private payor rate repeatedly by the same number of times as its volume. This is illustrated for Test 1 in Table 8.

TABLE 8—EXAMPLE OF THE CALCULATION OF THE WEIGHTED MEDIAN

	Test 1
	Private payor rate
Lowest (1)	$2.50
Lowest (2)	2.50
. . .	2.50
. . .	2.50
Until . . . (5,000)	2.50
Next Rate in Sequence (5,001)	4.00
Next Rate in Sequence (5,002)	4.00
. . .	4.00
. . .	4.00
Until (8,000)	4.00
. . .	. . .
Highest (11,000)	9.00

Thus, for Test 1, the array would show the lowest private payor rate of $2.50 five thousand times. The ellipsis (''. . .'') represents the continuation of the sequence between lines 2 and 4,999. The next private payor rate in the sequence ($4.00) would appear on line 5,001 and would be listed 3,000 times until we get to line 8,000. This process would continue with the remaining private payor rates listed as many times as the associated volumes, with the continuing sequence illustrated by ellipses. Continuing the array, the next highest private payor rate in the sequence would be: $5.00 listed 1,000 times; $6.00 listed 900 times; and $9.00 listed 1,100 times. The total number of lines in the array would be 11,000, as that is the total volume for Test 1 furnished for the five applicable laboratories. Because the total volume for Test 1 is 11,000, the weighted median private payor rate would be the

average of the 5,500th and 5,501st entry, which would be $4.00.

Repeating this process for Test 2 (see Table 9), the total volume for Test 2 is 7,600 units; therefore, the weighted median private payor rate would be the average of the 3,800th and 3,801st entry, which would be $18.00.

TABLE 9—TEST 2—SORTED BY RATE

Private payor rate	Volume
$18.00	4,000
20.00	2,000
23.50	1,000
25.00	500
30.00	100

For Test 3 (see Table 10), the total volume is 3,550 units; therefore, the weighted median private payor rate would be the average of the 1,775th and 1,776th entry, which would be $41.00.

TABLE 10—TEST 3—SORTED BY RATE

Private payor rate	Volume
$39.00	750
40.00	750
41.00	700
45.00	850
50.00	500

In this example, weighting changed the median private payor rate from $5.00 to $4.00 for Test 1, from $23.50 to $18.00 for Test 2, and resulted in no change ($41.00 both unweighted and weighted) for Test 3.

For simplicity, the above example shows only one private payor rate per test. We expect laboratories commonly have multiple private payor rates for each CDLT they perform. For each test performed by applicable laboratories having multiple private payor rates, we would use the same process shown above in this section, irrespective of how many different private payor rates there are for a given test. That is, we would list each private payor rate and its volume at that private payor rate, and determine the median as we did above for each payor and each laboratory, and then compute the volume-weighted median rate. The following example in Table 11 illustrates how we proposed to calculate the weighted median rate for a test under this scenario:

TABLE 11—TEST 4

	Payor 1		Payor 2		Payor 3	
	Private payor rate	Volume	Private payor rate	Volume	Private payor rate	Volume
Lab. A	$5.00	10	$5.25	20	$4.00	30
Lab. B	3.75	50				
Lab. C	6.00	5	5.00	10	5.50	25
Lab. D	5.00	10	4.75	30		
Lab. E	6.00	5				

To calculate the weighted median for Test 4, we would array all private payor rates, listed the number of times for each respective test's volume, and then determine the median value (as illustrated in Table 12).

TABLE 12—TEST 4—SORTED BY RATE

Private payor rate	Volume
$3.75	50
4.00	30
4.75	30
5.00	10
5.00	10
5.00	10
5.50	25
5.25	20
6.00	5
6.00	5

The total volume for Test 4 is 195. Therefore, the median value would be at the 98th entry, which would be $4.75. We proposed to describe this process in § 414.507(b).

Section 1834A(b)(1)(B) of the Act states that the Medicare payment amounts established under section 1834A of the Act shall apply to a CDLT furnished by a hospital laboratory if such test is paid for separately, and not as part of a bundled payment under section 1833(t) of the Act (the statutory section pertaining to the OPPS). In CY 2014, we finalized a policy to package certain CDLTs in the OPPS (78 FR 74939 through 74942 and § 419.2(b)(17)). Under current policy, certain CDLTs that are listed on the CLFS are packaged in the OPPS as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting on the same date of service as the laboratory test. Specifically, we conditionally package laboratory tests and only pay separately for a laboratory test when (1) it is the only service provided to a beneficiary on a given date of service or (2) it is conducted on the same date of service as the primary service, but is ordered for a different purpose than the primary service and ordered by a practitioner different than the practitioner who ordered the other OPPS services. Also excluded from this conditional packaging policy are molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 (78 FR 74939 through 74942). When laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid at the CLFS payment rates outside the OPPS under Medicare Part B. Section 1834A(b)(1)(B) of the Act would require us to pay the CLFS payment amount determined under section 1834A(b)(1)(B) of the Act for CDLTs that are provided in the hospital outpatient department and not packaged into Medicare's OPPS payment. This policy would apply to any tests currently paid separately in the hospital outpatient department or in the future if there are any changes to OPPS packaging policy.[2] As these are payment policies that pertain to the OPPS, we would implement them in OPPS annual rulemaking.

Next, section 1834A(b)(4)(A) of the Act states that the Medicare payment amounts under section 1834A(b) shall continue to apply until the year following the next data collection period. We proposed to implement this requirement in proposed § 414.507(a) by stating that each payment rate will be in effect for a period of 1 calendar year for ADLTs and 3 calendar years for all other CDLTs, until the year following the next data collection period.

Section 1834A(b)(4)(B) of the Act states that the Medicare payment amounts under section 1834A of the Act shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual

[2] For the CY 2016 OPPS final rule, we adopted changes to the packaging policy described above. See 80 FR 70348 for more information.

update, or other adjustment). The new payment methodology for CDLTs established under section 1834A(b) of the Act will apply to all tests furnished on or after January 1, 2018 (the revised implementation date we are adopting for the private payor rate-based CLFS) and replace the current methodology for calculating Medicare payment amounts for CDLTs under sections 1833(a), (b), and (h) of the Act, including the annual updates for inflation based on the percentage change in the CPI–U and reduction by a multi-factor productivity adjustment (see section 1833(h)(2)(A) of the Act). We stated in the proposed rule that we believed section 1834A(b)(4)(B) of the Act is clear that no annual update adjustment shall be applied for tests paid under section 1834A of the Act. Therefore, we proposed to include in § 414.507(c) that the payment amounts established under this section are not subject to any adjustment, such as any geographic, budget neutrality, annual update, or other adjustment.

A discussion of the public comments we received regarding the calculation of the weighted median private rate, and our responses to those comments, appears below.

Comment: Many commenters agreed with the calculation of the weighted median private payor rate outlined in the proposed rule but expressed concern about whether the calculated weighted median prices would reflect ''true market rates'' for laboratory services. For example, many commenters believed PAMA intended to include data from independent laboratories and hospital outreach laboratories when calculating the weighted median private payor rate for each laboratory test. Additionally, commenters contended that ''true market-based reimbursement rates'' can be calculated by defining an applicable laboratory as an entity identified by a CLIA number and not by TIN. To that end, the commenters recommended CMS revise the definition of applicable laboratory as an entity identified by a CLIA number so that independent laboratories and hospital outreach laboratories are included in the calculation of the weighted median private payor rates.

Response: In section II.A. of this final rule, we explain that we are defining applicable laboratory in terms of the NPI rather than the TIN and specifying in the definition that the majority of Medicare revenues threshold and the low expenditure threshold are to be applied by the NPI-level entity rather than by the TIN-level entity collectively with all its associated NPIs. A primary benefit of defining applicable laboratory at the NPI level, rather than at the TIN level, is that it will not prevent hospital outreach laboratories from meeting the definition of applicable laboratory and, therefore, reporting private rates. We also explained that we are not defining applicable laboratory by the CLIA certificate, in part, because CLIA certificates are not associated with Medicare billing so, unlike the NPI, with which revenues for specific services can easily be identified, the CLIA certificate cannot be used to identify revenues for specific services.

Independent laboratories that exceed the majority of Medicare revenues threshold and the low expenditure threshold will meet the definition of applicable laboratory and their applicable information will be reported to us for determining the weighted median private payor rate. Although the low expenditure threshold will exclude many independent laboratories and physician office laboratories from reporting private payor rates, based on our analysis of CY 2013 CLFS claims data, we found with a $12,500 threshold for a 6-month data collection period, we can retain a high percentage of Medicare FFS utilization data under the CLFS from applicable laboratories. We note that because CLFS payments will be based on the weighted median of private payor rates, additional reporting may not be likely to change the weighted median private payor rate, irrespective of how many additional smaller laboratories are required to report, if, as our analysis suggests, the largest laboratories dominate the market and therefore most significantly affect the payment rate. For more information regarding the definition of applicable laboratory, please see section II.A. of this final rule.

Comment: A few commenters requested that we calculate a weighted median private payor rate with and without data from Medicaid managed care organizations. These commenters opined that the effect of the inclusion of Medicaid managed care plans as private payors under the Act and their corresponding payment rates in the calculation of the weighted median is not yet fully known. They further indicated that determining the weighted median with and without Medicaid managed care plans will help us to assess the effect of setting Medicaid rates at a percentage of Medicare payment amounts over time.

Response: The statute requires the payment amount for laboratory tests paid under the new CLFS to be equal to the weighted median of private payor rates, and it explicitly includes in the definition of private payor, at section 1834A(a)(8)(c), Medicaid managed care organizations. Therefore, we do not believe we can apply a weighted median private payor rate for a test that we calculate without Medicaid managed care organization rates.

Comment: Two commenters requested clarification as to how we would address updating payment rates for tests which previously had multiple laboratories reporting private payor rates, but for which, in a subsequent data reporting period data is submitted by only one laboratory with low volume for the test. The commenters expressed concern that the updated payment rates would be based on a non-statistically significant amount of data reported for a test code(s). To that end, the commenters requested we ensure that a weighted median private payor rate represents data from more than one laboratory.

Response: Section 1834A(b)(2) of the Act requires the Secretary to calculate a weighted median private payor rate for each laboratory test for which information is reported for the data collection period by arraying the distribution of all private payor rates reported for the period for each test weighted by volume for each private payor and each laboratory. Section 1834A(b)(1)(A) of the Act requires the payment to be equal to the weighted median private payor rate for the test for the most recent data collection period. We do not see where the statute would permit us to deviate from that prescribed methodology in the situation where all the applicable information we receive for a test is reported by only one laboratory. Furthermore, in this final rule, we note that the statute specifies that only a single laboratory may offer and furnish an ADLT. Although for purposes of an ADLT we are revising the definition of a single laboratory to include entities that own or are owned by a laboratory, a single laboratory could conceivably consist of only one laboratory. Therefore, we cannot ensure that any data used to calculate a weighted median private payor rate represents more than one laboratory's private payor rate data.

Comment: One commenter requested clarification as to whether the new CLFS will have a national fee schedule amount for each laboratory test code or if the payment amounts will be adjusted locally by the MACs. The commenter also requested that we clarify whether the median private payor rate will be calculated from applicable information reported for tests furnished only to Medicare beneficiaries or will include private payor rates of tests furnished to commercial beneficiaries as well.

Response: Section 1834A(b)(4)(B) of the Act prohibits geographic adjustments of the new CLFS payment amounts. Therefore, the payment amounts under the revised CLFS will reflect a national fee schedule amount for each test. We also clarify that the applicable information reported is not limited to private payor rates for laboratory tests furnished to Medicare beneficiaries. Private payors, as we define the term at § 414.502, include health insurers, group health plans, Medicare Advantage plans, and Medicaid managed care organizations.

2. Phased-In Payment Reduction

Section 1834A(b)(3) of the Act limits the reduction in payment amounts that may result from implementation of the new payment methodology under section 1834A(b) of the Act within the first 6 years. Specifically, section 1834A(b)(3)(A) of the Act states that the payment amounts determined for a CDLT for a year cannot be reduced by more than the applicable percent from the preceding year for each of 2017 through 2022. Under section 1834A(b)(3)(B) of the Act, the applicable percent 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.

In the proposed rule (80 FR 59407), we provided the following example. If a test that is not a new ADLT or new CDLT has a CY 2016 Medicare payment amount of $20.00, the maximum reduction in the Medicare payment amount for CY 2017 is 10 percent, or $2. Following the CY 2016 data reporting period, CMS calculates a weighted median of $15.00 (a reduction of 25 percent from a Medicare payment amount of $20.00) based on the applicable information reported for the test. Because the maximum payment reduction permitted under the statute for 2017 is 10 percent, the Medicare payment amount for CY 2017 will be $18.00 ($20.00 minus $2.00). The following year, a 10 percent reduction from the CY 2017 payment of $18.00 would equal $1.80, lowering the total Medicare payment amount to $16.20 for CY 2018. In a second example we provided, if a test that is not a new ADLT or new CDLT has a CY 2016 Medicare payment amount of $17.00, the maximum reduction for CY 2017 is 10 percent or $1.70. Following the CY 2016 data reporting period, we calculated a weighted median of $15.00 (a reduction of 11.8 percent from the CY 2016 Medicare payment amount of $17). Because the maximum reduction is 10 percent, the Medicare payment amount for CY 2017 will be $15.30 or the maximum allowed reduction of $1.70 from the preceding year's (CY 2016) Medicare payment amount of $17.00. The following year (CY 2018), the Medicare payment amount will be reduced to $15.00, or $0.30 less, which is less than a 10 percent reduction from the prior year's (CY 2017) Medicare payment amount of $15.30. We believed applying the maximum applicable percentage reduction from the prior year's Medicare payment amount, rather than from the weighted median rate for CY 2016, was most consistent with the statute's mandate that the reduction ''for the year'' (that is, the calendar year) not be ''greater than the applicable percent . . . of the amount of payment for the test for the preceding year.''

We explained in the proposed rule that, to apply the phase-in reduction provisions beginning in CY 2017, we must look at the CLFS rates established for CY 2016 under the payment methodology set forth in sections 1833(a), (b), and (h) of the Act. Previously discussed, CDLTs furnished on or after July 1, 1984, and before January 1, 2017, in a physician's office, by an independent laboratory, or, in limited circumstances, by a hospital laboratory for its outpatients or non-patients, are paid under the Medicare CLFS, with certain exceptions. Payment is the lesser of:

- The amount billed;
- The state or local fee schedule amount established by Medicare contractors; or
- An NLA, which is a 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 tests for which the NLA was established before January 1, 2001. The NLA is 100 percent of the median of the local fee schedule amount for tests for which the NLA was first established on or after January 1, 2001 (see section 1833(h)(4)(B)(viii) of the Act). Medicare typically pays either the lower of the local fee schedule amount or the NLA, as it uncommon for the amount billed to be less than either of these amounts. As the local fee schedule amount may be lower than the NLA, Medicare payment amounts for CDLTs are not uniform across the nation. Thus, in the proposed rule we evaluated which CY 2016 CLFS payment amounts to consider—the lower of the local fee schedule amount or the NLA, or just the NLA—when applying the phase-in reduction provisions to the CLFS rates for CY 2017 (80 FR 59407). Under option 1, we explained we would apply the 10 percent reduction limitation to the lower of the NLA or the local fee schedule amount. This option would retain some of the features of the current payment methodology under sections 1833(a), (b), and (h) of the Act and, we believed, would be the most consistent with the requirement in section 1834A(b)(3)(A) of the Act to apply the applicable percentage reduction limitation to the ''amount of payment for the test'' for the preceding year. As noted above, for each of CY 2018 through 2022, we explained we would apply the applicable percentage reduction limitation to the Medicare payment amount for the preceding year. Under this option, though, the Medicare payment amounts may be local fee schedule amounts, so there could continue to be regional variation in the Medicare payment amounts for CDLTs.

Alternatively, under option 2, we explained would consider only the NLAs for CY 2016 when applying the 10 percent reduction limitation. This option would eliminate the regional variation in Medicare payment amounts for CDLTs, and, we believed, would be more consistent with section 1834A(b)(4)(B) of the Act, which, as noted above, prohibits the application of any adjustments to CLFS payment amounts determined under section 1834A of the Act, including any geographic adjustments.

We proposed option 2 (NLAs only) for purposes of applying the 10 percent reduction limit to CY 2017 payment amounts because we believed the statute intends CLFS rates to be uniform nationwide, which is why it precludes any geographic adjustment. That is, we proposed that if the weighted median calculated for a CDLT based on applicable information for CY 2017 would be more than 10 percent less than the CY 2016 NLA for that test, we would establish a Medicare payment amount for CY 2017 that is no less than 90 percent of the NLA (that is, no more than a 10 percent reduction). For each of CY 2018 through 2022, we would apply the applicable percentage reduction limitation to the Medicare payment amount for the preceding year.

We proposed to codify the phase-in reduction provisions in § 414.507(d) to specify that for years 2017 through 2022, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

- 2017—10 percent of the NLA for the test in 2016.
- 2018—10 percent of the payment rate established in 2017.
- 2019—10 percent of the payment rate established in 2018.

• 2020—15 percent of the payment rate established in 2019.

• 2021—15 percent of the payment rate established in 2020.

• 2022—15 percent of the payment rate established in 2021.

Table 13 illustrates the proposed phase-in reduction for the two hypothetical examples presented above:

TABLE 13—PHASE-IN REDUCTION FOR 2 EXAMPLES

	NLA	Private payor rate	10% maximum reduction	2017 rate	10% maximum reduction	2018 rate	10% maximum reduction	2019 rate
Test 1	$20.00	$15.00	$2.00	$18.00	$1.80	$16.20	$1.20 < 10%	$15.00
Test 2	17.00	15.00	1.70	15.30	0.30 < 10%	15.00	0.00 < 10%	15.00

Revised Phase-In of Payment Reduction Timetable

As discussed in section II.D., we are moving the implementation date of the private payor-based rates for the CLFS to January 1, 2018. We are finalizing our proposed policy for the phase-in of payment reductions, but we believe it is appropriate to make a corresponding change to the phase-in payment reduction timetable, which will permit laboratories to get the full benefit of the payment reduction limitations we believe the statute intended. Accordingly, we are revising the phase-in of the payment reductions timetable to reflect the January 1, 2018 implementation date of the revised CLFS. We are reflecting this change in § 414.507(d) by indicating that a maximum payment reduction per year of 10 percent applies for years 2018 through 2020 and a maximum payment reduction per year of 15 percent applies for years 2021 through 2023.

A discussion of the comments we received on the phase-in payment reduction, and our responses to those comments, appears below.

Comment: Two commenters requested clarification as to whether we would publish the full phased-in payment reductions, through CY 2022, when we publish the preliminary CLFS payment rates, or whether we would only publish the adjustment that would apply in January of the following year. The commenters believe it is important for laboratories to understand how payment reductions are applied to current Medicare payment rates over a three-year period to support laboratory planning over the course of several years.

Response: Under the private payor rate-based CLFS, the preliminary payment amounts we publish in September will reflect the full median private payor rate for each CDLT for a given update for the next calendar year. For example, if a test that is not a new ADLT or new CDLT has a CY 2017 national limitation amount (NLA) of $20.00, and we calculate a weighted median private payor rate of $15.00 following the CY 2017 data reporting period, the preliminary payment amount for CY 2018 would be $15.00 for the test. Laboratories will have the opportunity to review the fully phased-in payment reduction for a given CLFS update from the preliminary CLFS payment file. However, the final payment file published in November will only reflect the application of the phased-in payment reduction for the next calendar year.

Comment: One commenter requested clarification as to whether we will apply a maximum amount that a laboratory test's payment rate may increase over six years since there is a six-year limitation on the decrease, and whether we anticipate that laboratory rates will decrease in all circumstances. The commenter also requested clarification as to why the maximum decrease per year is needed.

Response: We are applying a phased-in payment reduction limitation as required by section 1834A(b)(3) of the Act. While the statute limits the amount of the payment reduction for laboratory tests, it does not limit the amount by which a laboratory test's payment rate may increase under the new CLFS, so we are not applying a limit on the increase amount. We cannot anticipate, as the commenter requested, whether payment rates for laboratory tests paid under the private payor rate-based CLFS will decrease in all circumstances. We note that, as discussed in the proposed rule (80 FR 59416), a study by the Office of Inspector General, ''Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings'' (OEI–07–11–00010, June 2013), showed Medicare paid between 18 and 30 percent more than other insurers for 20 high-volume and/or high-expenditure lab tests. We assumed the private payor rates to be approximately 20 percent lower than the Medicare CLFS payment rates for all tests paid under the CLFS. However, this aggregate assumption cannot be used to estimate the change in payment rates resulting from the private payor rate-based CLFS for a specific test(s).

3. Payment for New ADLTs

Section 1834A(d)(1)(A) of the Act provides that the payment amount for a new ADLT shall be based on the actual list charge for the laboratory test during an initial period of 3 quarters. Section 1834A(d)(2) of the Act requires applicable information to be reported for a new ADLT not later than the last day of the Q2 of the initial period. Section 1834A(d)(3) of the Act requires the Secretary to use the weighted median methodology under section (b) to establish Medicare payment rates for new ADLTs after the initial period. Under section 1834A(d)(3) of the Act, such payment rates continue to apply until the year following the next data collection period.

In this section, we discussed our proposal to require the initial period, which we proposed to call the ''new ADLT initial period,'' to begin on the first day of the first full calendar quarter following the first day on which a new ADLT is performed. In accordance with section 1834A(d)(1)(A) of the Act, we proposed that the payment amount for the new ADLT would equal the actual list charge, as defined below in this section, during the new ADLT initial period. Accordingly, we proposed to codify § 414.522(a)(1) to specify the payment rate for a new ADLT during the new ADLT initial period is equal to its actual list charge.

Section 1834A(d)(1)(B) of the Act states that actual list charge means the publicly available rate on the first day at which the test is available for purchase by a private payor for a laboratory test. We believed the ''publicly available rate'' is the amount charged for an ADLT that is readily accessible in such forums as a company Web site, 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. We noted that this interpretation of publicly available rate is distinguishable from a private payor rate in that the former is readily available to a consumer, while the latter may be negotiated between a private payor and

a laboratory and is not readily available to a consumer. We recognized there may be more than one publicly available rate, in which case we believed the lowest rate should be the actual list charge amount so that Medicare is not paying more than the lowest rate that is publicly available to any consumer. We proposed to define publicly available rate in § 414.502 as the lowest amount charged for an ADLT that is readily accessible in such forums as a company Web site, 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.

We explained in the proposed rule that, in our view, the first day a new ADLT is available for purchase by a private payor is the first day an ADLT is offered to a patient who is covered by private insurance. The statutory phrase ''available for purchase'' suggested to us that the test only has to be available to patients who have private insurance even if the test has not actually been performed yet by the laboratory. That is, it is the first day the new ADLT is obtainable by a patient, or marketed to the public as a test that a patient can receive, even if the test has not yet been performed on that date. We proposed to incorporate this interpretation into our proposed definition of actual list charge in § 414.502 to specify 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 test a patient can receive, even if the test has not yet been performed on that date.

Because we cannot easily know the first date on which a new ADLT is performed or the actual list charge amount for a new ADLT, we proposed to require the laboratory seeking ADLT status for its test to inform us of both the date the test is first performed and the actual list charge amount. Accordingly, we proposed in § 414.504(c), that, in its new ADLT application, the laboratory seeking new ADLT status for its test must attest to the actual list charge and the date the new ADLT is first performed. We also indicated that we would outline the new ADLT application process in detail in subregulatory guidance prior to the effective date of the private payor rate based CLFS.

Because 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 span of time between when the test is first performed and when the test is paid the actual list charge amount. We indicated in the proposed rule that we need to establish a payment amount for the test during that span of time. We explained that, similar to how we pay for a test under the PFS, the CLFS, or other payment systems, for a service that does not yet have a national payment amount, the MAC would work with a laboratory to develop a payment rate for a new ADLT for the period of time before we pay at actual list charge. We provided the following example in the proposed rule (80 FR 59408). If an ADLT is first performed on February 4, 2017, the new ADLT initial period would begin on April 1, 2017. While the new ADLT would be paid the actual list charge amount from April 1 through December 31, 2017, the MAC would determine the payment amount for the test from February 4 through March 31, 2017, as it does currently for tests that need to be paid prior to having a national payment amount. We proposed to specify at § 414.522(a)(2) that the payment amount for a new ADLT prior to the new ADLT initial period is determined by the MAC based on information provided by the laboratory seeking new ADLT status for its laboratory test.

According to section 1834A(d)(3) of the Act, the weighted median methodology used to calculate the payment amount for CDLTs that are not new ADLTs will be used to establish the payment amount for a new ADLT after the new ADLT initial period; we explained that the payment amount would be based on applicable information reported by an applicable laboratory before the last day of the second quarter of the new ADLT initial period, per section 1834A(d)(2) of the Act. We proposed to codify these provisions in § 414.522(b) as follows: After the new ADLT initial period, the payment rate for a new ADLT is equal to the weighted median established under the payment methodology described in § 414.507(b).

The payment rate based on the first 2 quarters of the new ADLT initial period would continue to apply until the year following the next data collection period, per section 1834A(d)(3) of the Act. The following is the example we provided in the proposed rule (80 FR 59408 through 59409) of how the various time frames for new ADLT payment rates would work. If the first day a new ADLT is available for purchase by a private payor is in the middle of Q1 of 2017, the new ADLT initial period would begin on the first day of Q2 of CY 2017. The test would be paid actual list charge through the end of Q4 of CY 2017. The applicable laboratory that furnishes the test would collect applicable information in Q2 and Q3 of CY 2017, and report it to us by the last day of Q3 of CY 2017. We would calculate a weighted median based on that applicable information and establish a payment rate that would be in effect from January 1, 2018, through the end of 2018. The applicable laboratory would report applicable information from the CY 2017 data collection period to us during the January through March data reporting period in 2018, which would be used to establish the payment rate that would go into effect on January 1, 2019.

A discussion of the comments we received on payment for new ADLTs, and our responses to those comments, appears below.

Comment: Two commenters noted that the statute defines actual list charge as the publicly available rate on the first day at which the test is available for purchase by a private payor. The commenter requested that we adopt that statutory definition, which the commenter believe is clear and gives laboratories sufficient guidance, rather than expand upon the statutory definition of actual list charge.

Response: We believe we need to interpret several phrases in the statutory definition of actual list charge—''publicly available rate'' and ''available for purchase''—without which the industry would not have a common and consistent understanding of how we are implementing the actual list charge requirement. As discussed in the proposed rule (80 FR 59408), it is our understanding that if a test is ''available for purchase,'' the test does not have to have been performed yet; it only has to be available to patients who have private insurance. Further, our definition of ''publicly available rate'' in § 414.502 illustrates that we mean the lowest amount charged that is readily accessible to the public.

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

Section 1834A(d)(4) of the Act requires that, if the Medicare payment amount during the new ADLT initial period (that is, the actual list charge) is determined to be more than 130 percent of the Medicare payment amount based on the weighted median of private payor rates that applies after the new ADLT initial period, the Secretary shall recoup the difference between such payment amounts for tests furnished during such period.

In the proposed rule, we interpreted this to mean that the Secretary should recoup the entire amount of the difference between the Medicare

payment amount during the new ADLT initial period and the Medicare payment amount based on the weighted median of private payor rates—not the difference between the Medicare payment amount during the initial period and 130 percent of the weighted median rate. In the proposed rule, we noted as an example, if the Medicare payment amount using actual list charge is $150 during the new ADLT initial period and the weighted median rate is $100, the Medicare payment amount for the new ADLT initial period is 150 percent of the Medicare payment amount based on the weighted median rate. We believed the statute directed the Secretary to use 130 percent as the threshold for invoking the recoupment provision but once invoked, collect the entire amount of the difference in Medicare payment amounts ($50 in this example).

The statute refers to ''such payment amounts'' which we interpreted to mean the Medicare payment amount based on actual list charge and the Medicare payment amount based on the weighted median rate. We believed that the statute directed recoupment of the full amount of that difference as the 130 percent is only being used in making the threshold determination of whether the recoupment provision will apply. For this reason, we proposed at § 414.522(c) to specify that if the Medicare payment amount for an ADLT during the new ADLT initial period (based on actual list charge) was more than 130 percent of the weighted median rate, we would recoup the entire amount of the difference between the two amounts. We further noted that if the 130 percent statutory threshold is not exceeded, we would not make any recoupment at all. Thus, for instance, if the weighted median private payor rate is $100 and the Medicare payment amount during the initial period is $130 or lower, the statutory threshold of 130 percent would not be exceeded and we would not pursue any recoupment of payment.

However, if the actual list charge for a new ADLT was more than 130 percent of the weighted median rate (as calculated from applicable information received during the first reporting period), claims paid during the new ADLT initial period would be re-priced using the weighted median rate. To that end, we proposed that we would issue a Technical Direction Letter instructing the MACs to re-price claims previously paid during the new ADLT initial period at the weighted median rate (instead of the actual list charge for the new ADLT). We also noted that we intended to issue further guidance on the operational procedures for recoupment of payments for the new ADLTs that exceed the 130 percent threshold.

A discussion of the comments we received on our proposed recoupment of payment for new ADLTs and our responses to those comments, appears below.

Comment: A few commenters disagreed with our proposal to recoup the difference between the actual list charge and the weighted median private payor rate if the actual list charge is greater than 130 percent of the weighted median private payor rate. The commenters stated that Congress intended to reimburse new ADLTs *up to* 130 percent of the weighted median private payor amount, and the recoupment should serve as a guardrail that prevents abusive laboratory pricing. Additionally, the commenters contended that sound public policy, as well as a natural reading of the statute, dictates that Medicare regard the recoupment provision as an outer boundary limiting the actual list charge. To that end, the commenters requested that CMS recoup the difference *between* the actual list charge and 130 percent of the weighted median private payor rate, rather than the difference between the actual list charge and 100 percent of the weighted median private payor rate.

Other stakeholders stated that our proposed recoupment policy would provide a disincentive for laboratories offering new ADLTs to negotiate price concessions with private payors. For example, they believe that if laboratories performing new ADLTs negotiate price concessions with commercial payors, it will lower the weighted median private payor rate and make it more likely that the ADLT will reach the 130 percent recoupment threshold. Therefore, laboratories offering new ADLTs may refuse to negotiate price concessions with commercial payors to avoid the recoupment threshold.

Response: As discussed in this section, we proposed to recoup the entire amount of the difference between the actual list charge and the weighted median private payor rate if the actual list charge is greater than 130 percent of the weighted median private payor rate. We did so because, while we acknowledged in the proposed rule that the statute could be interpreted to permit the Secretary to recoup the difference between the Medicare payment amount during the initial period and 130 percent of the weighted median rate, we believed that the more straightforward interpretation directed the Secretary to recoup the entire amount. Under our proposed policy, if the difference between actual list charge and the weighted median private payor rate was not greater than 130 percent, the recoupment provision would not apply and the test would be paid at the ''actual list charge'' during the entire new ADLT initial period.

After review of the public comments, we recognize our proposed policy would create a disparity in the application of recoupment of payments. Under our proposal, if the difference between the actual list charge and the weighted median private payor rate is not greater than 130 percent (for example, if it is exactly 130 percent), then there would be no recoupment, but if the difference between the actual list charge and the weighted median private payor rate is greater than 130 percent (for example, if it is 131 percent), then the entire amount of the difference between actual list charge and the weighted median private payor rate would be recouped.

In section II.D. of this final rule, we indicated that we understand a Medicare coverage determination could be a lengthy process for the types of tests that are likely to qualify as ADLTs and that, consequently, a test may be available on the market and paid by private payors before Medicare covers and pays for it. If a test is available to the public long before a Medicare Part B coverage determination is made and ADLT status is granted, the actual list charge could be significantly higher than the weighted median private payor rate based on 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, under our proposed recoupment policy, we would have recouped the entire difference between the actual list charge and the weighted median private payor rate, in which case the single laboratory that develops, offers and furnishes the ADLT would not have been awarded any special payment status during the new ADLT initial period, as contemplated by the statute. Furthermore, we agree our proposed recoupment policy could have been a disincentive for laboratories and private payors to negotiate price concessions because it could have increased the likelihood that the recoupment threshold would have been met.

For these reasons, we are revising our proposed interpretation of the recoupment provision so that during the new ADLT initial period, new ADLTs will be paid up to 130 percent of their weighted median private payor rate. To determine whether the recoupment provision applies, we 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, we will recoup the difference between the actual list charge and 130 percent of the weighted median private payor rate. We are revising payment for new ADLTs at § 414.522(c) to codify this change from the proposed rule.

Additionally, as discussed in section II.D., we revised the definition of 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 us. See section II.D. for a discussion of the new ADLT initial period.

5. Payment for Existing ADLTs

Section 1834A(i) of the Act requires the Secretary, for the period of April 1, 2014, through December 31, 2016, to use the methodologies for pricing, coding, and coverage for ADLTs in effect on the day before the enactment of PAMA (April 1, 2014), and provides that those methodologies may include crosswalking or gapfilling. Thus, we explained that section 1834A(i) of the Act authorizes us to use crosswalking and gapfilling to pay for existing ADLTs, that is, those ADLTs that are paid for under the CLFS prior to January 1, 2017. The methodologies in effect on March 31, 2014 were gapfilling and crosswalking. Therefore, we proposed to use crosswalking and gapfilling to establish the payment amounts for existing ADLTs. We proposed to reflect this requirement at § 414.507(h) to state that for ADLTs that are furnished between April 1, 2014 and December 31, 2016, payment is made based on crosswalking or gapfilling methods described in proposed § 414.508(a).

A discussion of the comments we received on payment for existing ADLTs, and our responses to those comments, appears below.

Comment: A few commenters recommended that we use the existing MAC rates for existing ADLTs instead of gapfilling or crosswalking pricing methods.

Response: We disagree with the suggestion to use existing MAC rates for pricing existing ADLTs. We believe the purpose of PAMA is for the CLFS to reflect changes in market prices over time, which would not be accomplished by carrying over a previous payment amount. Therefore, we are finalizing the use of crosswalking and gapfilling methodologies for establishing a payment amount for existing ADLTs.

As we discuss in section II.D. of this final rule, in response to comments, we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. In conjunction with the revised implementation date, we are also adopting a corresponding change for new ADLTs to reflect that a new ADLT is an ADLT for which payment has not 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 31, 2017, instead of December 31, 2016, which is reflected in revised § 414.507(h).

6. Payment for New CDLTs That Are Not ADLTs

Section 1834A(c) of the Act includes special provisions for determining payment for new CDLTs that are not ADLTs. Section 1834A(c)(1) of the Act states that payment for a CDLT that is assigned a new or substantially revised HCPCS code on or after the April 1, 2014 enactment date of PAMA, which is not an ADLT, will be determined using crosswalking or gapfilling during an initial period until payment rates under section 1834A(b) of the Act are established. The test must either be crosswalked (as described in § 414.508(a) or any successor regulation) to the most appropriate existing test on the CLFS or, if no existing test is comparable, paid according to a gapfilling process that takes into account specific sources of information, which we describe later in this section.

We developed our current procedures for crosswalking and gapfilling new CDLTs pursuant to section 1833(h)(8) of the Act. Section 1833(h)(8)(A) of the Act requires the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any CDLT for which a new or substantially revised HCPCS code is assigned on or after January 1, 2005. Section 1833(h)(8)(B) of the Act specifies the annual public consultation process that must take place before the Secretary can determine payment amounts for such tests, and section 1833(h)(8)(C) of the Act requires the Secretary to implement the criteria for making such determinations and make available to the public the data considered in making such determinations. We implemented these provisions in the CY 2007 PFS final rule (71 FR 69701 through 69704) published in the **Federal Register** on December 1, 2006.

We interpreted section 1834A(c) of the Act to generally require us to use the existing procedures we implemented in 42 CFR part 414, subpart G. However, we explained that we needed to make some changes to our current regulations to reflect specific provisions in section 1834A(c) of the Act, as well as other aspects of section 1834A of the Act and the proposed rule. In this section, we describe those proposed changes and how they would affect our current process for setting payment rates for new CDLTs. To incorporate section 1834A of the Act within the basis and scope of payment for CDLTs, we proposed to add a reference to 42 CFR part 414, subpart A, entitled ''General Provisions,'' in § 414.1.

In addition, we proposed to change the title of 42 CFR part 414, subpart G, to reflect that it applies to payment for all CDLTs, not just new CDLTs. We also proposed to add a reference to section 1834A of the Act in § 414.500. To reflect that § 414.500 would apply to a broader scope of laboratory tests than just those covered by section 1833(h)(8) of the Act, we proposed to remove ''new'' and ''with respect to which a new or substantially revised Healthcare Common Procedure Coding System code is assigned on or after January 1, 2005.''

a. Definitions

As previously noted, section 1834A(c) of the Act addresses payment for a CDLT that is not an ADLT and that is assigned a new or substantially revised HCPCS code on or after April 1, 2014, PAMA's enactment date. Our current regulations apply throughout to a ''new test,'' which we currently define in § 414.502 as any CDLT for which a new or substantially revised HCPCS code is assigned on or after January 1, 2005. We proposed to replace ''new test'' with ''new CDLT'' in § 414.502 and to make conforming changes throughout the regulations to distinguish between the current requirements that apply to new tests and the proposed requirements that would apply to new CDLTs. Our proposed definition specified that a new CDLT means a CDLT that is assigned a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code, and that does not meet the definition of an ADLT. Section 1834A(c)(1) of the Act uses the same terminology as section 1833(h)(8)(A) of the Act, ''new or substantially revised HCPCS code,'' which we incorporated into the definition of new test in § 414.502. We also defined ''substantially revised HCPCS code'' in

§ 414.502 based on the statutory definition in section 1833(h)(8)(E)(ii) of the Act to mean a code for which there has been a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test). Because section 1834A(c)(1) of the Act uses terminology that we have already defined, and is consistent with our current process, we did not propose any changes to the phrase ''new or substantially revised HCPCS code'' in our proposed definition of new CDLT or to the existing definition for ''substantially revised HCPCS code.''

We did not receive any comments on our proposed payment for new CDLTs that are not ADLTs or the proposed definitions discussed above.

b. Crosswalking and Gapfilling

Background: As we explained in the CY 2008 PFS final rule with comment period (71 FR 66275 through 66276), under current § 414.508, we use one of two bases for payment to establish a payment amount for a new test. Under § 414.508(a), the first basis, called ''crosswalking,'' is used if a new test is determined to be comparable to an existing test, multiple existing test codes, or a portion of an existing test code. If we use crosswalking, we assigned to the new test code the local fee schedule amount and NLA of the existing test code or codes. If we crosswalk to multiple existing test codes, we determine the local fee schedule amount and NLA based on a blend of payment amounts for the existing test codes. Under § 414.508(a)(2), we pay the lesser of the local fee schedule amount or the NLA. The second basis for payment is ''gapfilling.'' Under § 414.508(b), we use gapfilling when no comparable existing test is available. We instruct each MAC to determine a contractor-specific amount for use in the first year the new code is effective. (We note that we proposed to replace ''carrier'' with ''contractor'' to reflect that Medicare has replaced fiscal intermediaries and carriers with MACs.) The sources of information MACs examine in determining contractor-specific amounts include:

- Charges for the test and routine discounts to charges;
- Resources required to perform the test;
- Payment amounts determined by other payors; and
- Charges, payment amounts, and resources required for other tests that may be comparable (although not similar enough to justify crosswalking) or otherwise relevant.

During the first year a new test code is paid using the gapfilling method, contractors are required to establish contractor-specific amounts on or before March 31. Contractors may revise their payment amounts, if necessary, on or before September 1, based on additional information. After the first year, the contractor-specific amounts are used to calculate the NLA, which is the median of the contractor-specific amounts, and under § 414.508(b)(2), the test code is paid at the NLA in the second year. We instruct MACs to use the gapfilling method through program instruction, which lists the specific new test code and the timeframes to establish contractor-specific amounts.

In the CY 2007 PFS final rule with comment period (71 FR 69702), we also described the timeframes for determining the amount of and basis for payment for new tests. The codes to be included in the upcoming year's fee schedule (effective January 1) are available as early as May. We list the new clinical laboratory test codes on our Web site, usually in June, along with registration information for the public meeting, which is held no sooner than 30 days after we announce the meeting in the **Federal Register**. The public meeting is typically held in July. In September, we post our proposed determination of the basis for payment for each new code and seek public comment on these proposed determinations. The updated CLFS is prepared in October for release to our contractors during the first week in November so that the updated CLFS is ready to pay claims effective January 1 of the following calendar year. Under § 414.509, for a new test for which a new or substantially revised HCPCS code was assigned on or after January 1, 2008, we accept reconsideration requests in written format for 60 days after making a determination of the basis for payment (either crosswalking or gapfilling) regarding whether we should reconsider the basis for payment and/or amount of payment assigned to the new test. If a requestor recommends that the basis for payment should be changed from gapfilling to crosswalking, the requestor may also recommend the code or codes to which to crosswalk the new test. The reconsideration request would be presented for public comment at the next public meeting, the following year. After considering the public comments, if we decide to change the amount of payment for the code, the new payment amount would be effective January 1 of the year following the reconsideration.

c. Proposal

Section 1834A(c)(1) of the Act refers to payment for CDLTs for which a new or substantially revised HCPCS code is assigned on or after the April 1, 2014 PAMA enactment date. We noted in the proposed rule (80 FR 59410) that the annual crosswalking and gapfilling process had already occurred for codes on the 2015 CLFS, and was currently underway for codes on the 2016 CLFS. We proposed to continue using the current crosswalking and gapfilling processes for CDLTs assigned new or substantially revised HCPCS codes prior to January 1, 2017 because:

- Section 1834A(c)(1)(A) of the Act refers to our existing crosswalking process under § 414.508(a);
- We would not be able to finalize new crosswalking requirements as of PAMA's April 1, 2014 enactment date; and
- The current payment methodology involving NLAs and local fee schedule amounts would remain in effect until January 1, 2017.

We proposed to update § 414.508 by changing the introductory language to limit paragraphs (a) and (b) (which would be redesignated as paragraphs (a)(1) and (2)) to tests assigned new or substantially revised HCPCS codes ''between January 1, 2005 and December 31, 2016,'' and adding introductory language preceding new proposed paragraphs (b)(1) and (2) to reflect our proposal to pay for a CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2017 based on either crosswalking or gapfilling.

For CDLTs that are assigned a new or substantially revised HCPCS codes on or after January 1, 2017, we proposed to use comparable crosswalking and gapfilling processes that were modified to reflect the new market-based payment system under section 1834A of the Act. We noted in the proposed rule that, beginning January 1, 2017, the payment methodology established under section 1834A(b) of the Act would replace the current payment methodology under sections 1833(a), (b), and (h) of the Act, including NLAs and local fee schedule amounts. Thus, we proposed to establish § 414.508(b)(1) and (2) to describe crosswalking and gapfilling processes that do not involve NLAs or local fee schedule amounts.

Regarding the crosswalking process, because section 1834A(c)(1)(A) of the Act specifically references our existing process under § 414.508(a), we did not propose to change the circumstances when we use crosswalking, that is, when we determine the new CDLT is

comparable to an existing test, multiple existing test codes, or a portion of an existing test code. For a CDLT assigned a new or substantially revised HCPCS code on or after January 1, 2017, we proposed to establish the following crosswalking process in § 414.508(b)(1), which does not rely on NLAs or local fee schedule amounts:

d. Crosswalking and Gapfilling

Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

- We assign to the new CDLT code, the payment amount established under § 414.507 for the existing test.
- Payment for the new CDLT code is made at the payment amount established under § 414.507 for the existing test.

Regarding the gapfilling process, section 1834A(c)(2) of the Act requires the use of gapfilling if no existing test is comparable to the new test. Section 1834A(c)(2) of the Act specifies that this gapfilling process must take into account the following sources of information to determine gapfill amounts, if available:

- 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.
- Other criteria the Secretary determines appropriate.

The first four criteria are identical to the criteria currently specified in § 414.508(b)(1). For this reason did not propose any substantive changes to the factors that must be considered in the gapfilling process. The fifth criterion authorizes the Secretary to establish other criteria for gapfilling as the Secretary determines appropriate. We did not propose any additional factors to determine gapfill amounts. We noted that, if we decided to establish additional gapfilling criteria, we would do so through notice and comment rulemaking.

We proposed 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 reference to the NLA in § 414.508(b)(2), as that term would no longer be applicable, and would substitute ''Medicare Administrative Contractor'' (MAC) for ''carrier,'' as MACs are now Medicare's claims processing contractors. To determine a payment amount under this gapfilling process, we proposed to pay the test code at an amount equal to the median of the contractor-specific payment amounts, consistent with the current gapfilling methodology at § 414.508(b). We proposed § 414.508(b)(2) would state that gapfilling is used when no comparable existing CDLT is available. We proposed in § 414.508(b)(2)(i) that, in the first year, Medicare Administrative Contractor-specific amounts would be established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

- Charges for the test and routine discounts to charges;
- Resources required to perform the test;
- Payment amounts determined by other payors; and
- Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.
- Other criteria CMS determines appropriate.

We proposed in § 414.508(b)(2)(ii) that, in the second year, the CDLT code would be paid at the median of the MAC-specific amounts.

We noted that section 1834A(c)(1) of 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) of the Act are established. As discussed, we typically list new CDLT codes on our Web site by June, and by January 1 of the following calendar year, we have either established payment amounts using crosswalking or indicated that a test is in its first year of the gapfilling process. Because we proposed to largely continue our existing gapfilling and crosswalking processes, for CDLTs assigned new or substantially revised HCPCS codes on or after January 1, 2017, we believed the initial period should be the period of time until applicable information is reported for a CDLT and can be used to establish a payment amount using the weighted median methodology in § 414.507(b). We proposed to continue to permit reconsideration of the basis and amount of payment for CDLTs as we currently do under § 414.509. For a new CDLT for which a new or substantially revised HCPCS code was assigned on or after January 1, 2008, we accept reconsideration requests in written format for 60 days after making a determination of the basis for payment (either crosswalking or gapfilling) or the payment amount assigned to the new test code, per § 414.509(a)(1), (b)(1)(i) and (b)(2)(ii). The requestor may also request to present its reconsideration request at the next annual public meeting, typically convened in July of each year under § 414.509(a)(2)(i) and (b)(1)(ii)(A). Under § 414.509(a)(1), if a requestor recommends that the basis for payment should be changed from gapfilling to crosswalking, the requestor may also recommend the code or codes to which to crosswalk the new test. We noted that we might reconsider the basis for payment under § 414.509(a)(3) and (b)(1)(iii) or its determination of the amount of payment, which could include a revised NLA for the new code under § 414.509(b)(2)(v) based on comments. However, as noted in this section, we explained in the proposed rule that the NLA would no longer be applicable on or after January 1, 2017, and we would instead refer to the national payment amount under crosswalking or gapfilling as the median of the contractor-specific payment amounts. Therefore, we proposed to revise § 414.509 to replace references to the ''national limitation amount'' with ''median of the Medicare Administrative Contractor-specific payment amount'' in § 414.509(b)(2)(iv) and (b)(2)(v). We also proposed to replace ''carrier-specific amount'' where it appears in § 414.509 with ''Medicare Administrative Contractor-specific payment amount'' because we now refer to our Medicare Part B claims processing contractors as Medicare Administrative Contractors.

As we discuss in this final rule, in response to comments, we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. We believe it is also appropriate for us to adopt corresponding changes to several timeframes we proposed in § 414.508. We are replacing December 31, 2016, with December 31, 2017 in the introductory paragraph of § 414.508(a) to indicate, for a new CDLT that is assigned a new or substantially revised code between January 1, 2005 and December 31, 2017, we determine the payment amount based on either crosswalking or gapfilling, as specified in paragraph (a)(1) or (2). We are also replacing January 1, 2017, with January 1, 2018 in the introductory paragraph of § 414.508(b) to indicate, for a new CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2018, we determine the payment amount based on either crosswalking or

gapfilling, as specified in paragraph (b)(1) or (2).

A discussion of the comments we received on crosswalking and gapfilling and our responses to those comments appears below.

Comment: One commenter requested that we modify the gapfilling process for establishing a payment amount for CDLTs assigned new or substantially revised HCPCS codes to more accurately account for the resources required to perform a test. To that end, the commenter suggested that laboratories be required to submit ''laboratory methods'' to the MACs for an assessment of the steps required to perform the new and/or previously unpriced test as part of the requirement that contractors take into consideration the resources required to perform a test when determining a gapfill payment amount.

Response: We appreciate the commenter's suggestions for making revisions to the gapfill methodology. However, we believe our gapfill methodology, revised to reflect section 1834A(c)(2) of the Act, is sufficient for establishing the CLFS payment amount for new CDLTs that are not ADLTs. Under the gapfill criteria, MACs are permitted to take into account laboratory methods, and we trust they will do so if they believe it is necessary. If we determine that additional changes are necessary to establish payment amounts for new CDLTs under the revised CLFS, we may propose modifications to our policies, which we would do through notice and comment rulemaking.

e. Public Consultation Procedures

(1) Advisory Panel Recommendations

Our current procedures for public consultation for payment for a new test are addressed in § 414.506. Section 1834A(c)(3) of the Act requires the Secretary to consider recommendations from the expert outside advisory panel established under section 1834A(f)(1) of the Act when determining payment using crosswalking or gapfilling processes. In this section, we describe the Advisory Panel on CDLTs (the Panel). We proposed to specify that the public consultation process regarding payment for new CDLTs on or after January 1, 2017, must include the Panel's recommendations by adding § 414.506(e) to specify that we will consult with an expert outside advisory panel, called the Advisory Panel on CDLTs, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics in issues related to CDLTs . We proposed that this advisory panel would provide input on the establishment of payment rates under § 414.508 and provide recommendations to CMS under this subpart.

A discussion of the comments we received on the Panel is included in section II.J.1. of this final rule.

(2) Explanation of Payment Rates

Section 1834A(c)(4) of the Act requires the Secretary to make available to the public an explanation of the payment rate for a new CDLT, including an explanation of how the gapfilling criteria are applied and how the recommendations of the Advisory Panel on CDLTs are applied. Currently, § 414.506(d) provides that, considering the comments and recommendations (and accompanying data) received at the public meeting, we develop and make available to the public (through a Web site and other appropriate mechanisms) a list of:

- Proposed determinations of the appropriate basis for establishing a payment amount for each code, with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments within a specified time period on the proposed determinations; and
- Final determinations of the payment amounts for tests, with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public.

Section 414.506(d) already indicates that we will provide an explanation of the payment rate determined for each new CDLT and the rationale for each determination. As described above, under our current process, we make available to the public proposed payment rates with accompanying rationales and supporting data, as well as final payment rates with accompanying rationales and supporting data. However, this process has been used almost exclusively for new tests that are crosswalked. For tests that are gapfilled, we generally post the contractor-specific amounts in the first year of gapfilling on the CMS Web site and provide for a public comment period, but do not typically provide explanations of final payment amounts. Based on section 1834A(c)(4) of the Act, we proposed to amend § 414.506 to explicitly indicate that, for a new CDLT on or after January 1, 2017, we would provide an explanation of gapfilled payment amounts and how we took into account the Panel's recommendations. Specifically, we proposed to add paragraphs (3) and (4) to § 414.506(d). In § 414.506(d)(3), we proposed to specify that, for a new CDLT, in applying paragraphs (d)(1) and (2), we will provide an explanation of how we took into account the recommendations of the Advisory Panel on CDLTs. In § 414.506(d)(4), we proposed to specify that, for a new CDLT, in applying paragraphs (d)(1) and (2) and § 414.509(b)(2)(i) and (iii) when we use the gapfilling method described in § 414.508(b)(2), we will make available to the public an explanation of the payment rate for the test.

Under these provisions, we proposed to publish the Medicare payment amounts for new CDLTs along with an explanation of the payment rate and how the gapfilling criteria and recommendations by the Advisory Panel on CDLTs were applied via the CMS CLFS Web site as we currently do for new tests. The CMS CLFS Web site may be accessed at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/.*

As we discuss in this final rule, we are moving the implementation date of the private payor rate-based CLFS until January 1, 2018. We believe it is also appropriate for us to adopt corresponding changes to several timeframes we proposed in § 414.506. Accordingly, in § 414.506(d)(3) and (4), we are replacing January 1, 2017 with January 1, 2018 to identify our obligations with respect to procedures for public consultation for payment for new CDLTs beginning January 1, 2018.

Comment: We received a few comments supporting our proposal to publish an explanation of payment rates.

Response: We appreciate the commenters' support.

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

While sections 1834A(b), (c), and (d), of the Act, respectively, address payment for CDLTs and ADLTs as of January 1, 2017, the statute does not address how we must pay for a laboratory test when no applicable information is reported for applicable laboratories.

There are several possible reasons why no applicable information would be reported for a laboratory test. For example:

- *Test is Not Performed for Any Privately Insured Patients During the Data Collection Period.* One reason we may not receive any applicable information is that the test is not performed for a privately insured

patient by an applicable laboratory during the data collection period.

• *Test is Not Performed by Any Applicable Laboratories.* Another reason why we may not receive applicable information is that none of the laboratories performing the test during a data collection period are applicable laboratories as defined in proposed § 414.502. For example, the laboratories could be hospital laboratories that, in a data collection period, did not meet the majority of Medicare revenues threshold or the low expenditure threshold. We estimated that in 2013 there were about 17 laboratory tests with utilization completely attributed to entities that would not have been applicable laboratories because they did not meet the low expenditure threshold.

• *Special Situations Involving ADLTs.* It is also possible that a laboratory that performs a test that would qualify as an ADLT, does not meet the definition of an applicable laboratory and, therefore, no applicable information could be reported for it. As discussed in this section, an ADLT is a test that is performed by only a single laboratory. If that laboratory is not an applicable laboratory, we would not receive applicable information for the test. As discussed above in this final rule, this situation could occur if the only laboratory performing the test did not meet the majority of Medicare revenue threshold or the low expenditure threshold. A discussion of the majority of Medicare revenues threshold and low expenditure threshold is included in section II.A. of this final rule.

• *Other Possible Reasons.* It is possible we may not receive applicable information for a laboratory test if a reporting entity fails to comply with the reporting requirements under section 1834A of the Act, in which case penalties under section 1834A(a)(9) of the Act may be applied. There may also be other reasons we cannot anticipate where we might not receive applicable information for a laboratory test in a data reporting period.

In the event we do not receive applicable information for a laboratory test that is paid under the CLFS, we would need to determine a payment amount for the test in the year following the data collection period. The statute does not specify the methodology we must use to establish the payment rate for an ADLT or CDLT for which we receive no applicable information in a data reporting period but for which we need to establish a payment amount. In such circumstances, we proposed to use crosswalking and gapfilling using the requirements we proposed for those methodologies in § 414.508(b)(1) and (2) to establish a payment rate on or after January 1, 2017 (which will now be January 1, 2018, in accordance with the change to the implementation date of the revised CLFS), which would remain in effect until the year following the next data reporting period. We proposed this policy would include the situation where we receive no applicable information for tests that were previously priced using gapfilling or crosswalking or where we had previously priced a test using the weighted median methodology. If we receive no applicable information in a subsequent data reporting period, we propose to use crosswalking or gapfilling methodologies to establish the payment amount for the test. That is, if in a subsequent data reporting period, no applicable information is reported, we would reevaluate the basis for payment, —crosswalking or gapfilling— and the payment amount for the test.

In exploring what we would do if we receive no applicable information for a CDLT, we alternatively considered carrying over the current payment amount for a test under the current CLFS, the payment amount for a test (if one was available) using the weighted median methodology based on applicable information from the previous data reporting period, or the gapfilled or crosswalked payment amount. However, we did not propose this approach because we believed carrying over previous payment rates would not reflect changes in costs or pricing for the test over time. We understood the purpose of section 1834A of the Act to be update the CLFS rates to reflect changes in market prices over time.

As noted above, the statute does not address situations where we price a test using crosswalking or gapfilling because we received no applicable information with which to determine a CLFS rate. We believed reconsidering rates for tests in these situations would be consistent with the purpose of section 1834A of the Act, which requires us to periodically reconsider CLFS payment rates. In the case of tests for which we previously received applicable information to determine payment rates, section 1834A of the Act requires Medicare to follow changes in the market rates for private payors. Our proposal served an analogous purpose by having us periodically reconsider the payment rate of a test using gapfilling or crosswalking. We stated in the proposed rule that we expected to continue to evaluate our proposed approach to setting rates for laboratory tests paid on the CLFS with no reported applicable information as we gained more programmatic experience under the new CLFS. We indicated that any revisions to how we determine a rate for laboratory tests without reported applicable information would be addressed in the future through notice and comment rulemaking.

In summary, we proposed that for a CDLT, including ADLTs, for which we receive no applicable information in a data reporting period, we would determine the payment amount based on either crosswalking or gapfilling. We proposed to add paragraph (g) to § 414.507 to specify that for CDLTs for which we receive no applicable information, payment would be made based on the crosswalking or gapfilling methods described in § 414.508(b)(1) and (2).

A discussion of the comments we received on Medicare payment for tests where no applicable information is reported, and our responses to those comments, appears below.

Comment: A few commenters suggested that we carry over prices for any tests for which we receive no private payor data during a data reporting period. They contended that simply carrying over the payment amount established for the previous update would be a more logical approach than reevaluating the payment basis (crosswalk versus gapfill) for a test for which payment had once been established.

Response: As discussed previously, we considered carrying over the current payment amount for a test in the event we do not receive any applicable information for a test in a given data reporting period. However, we are not adopting that approach because we understand the purpose of the revised CLFS payment methodology is to update the CLFS rates to reflect changes in market prices over time, and we believe carrying over previous payment rates would not reflect changes in costs or pricing for the test over time.

As we discussed previously, because we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018, we are also adopting a corresponding change to the use of crosswalking and gapfilling methodologies for tests where no applicable information is reported. That is, we are revising § 414.508(a) to reflect that we will use the crosswalking and gapfilling methodologies specified in that section to establish payment rates before January 1, 2018, and we are revising § 414.508(b) to reflect that we will use the crosswalking and gapfilling methodologies specified under § 414.508(b) to establish payment rates beginning January 1, 2018.

In summary, we are revising our proposed policy for recouping payment for new ADLTs if the actual list charge paid during the new ADLT initial period exceeds 130 percent of the market-based rate as discussed above in this section. If the actual list charge is greater than 130 percent of the weighted median private payor rate determined during the new ADLT initial period, we will recoup the difference between the actual list charge and 130 percent of the weighted median private payor rate. We are also making changes corresponding to the January 1, 2018 implementation date of the private payor rate-based CLFS as discussed in this section. We are finalizing all other payment methodology policies in this section as proposed.

I. Local Coverage Determination Process and Designation of Medicare Administrative Contractors for Clinical Diagnostic Laboratory Tests

Section 1834A(g) of the Act addresses issues related to coverage of CDLTs. Section 1834A(g)(1)(A) of the Act requires that coverage policies for CDLTs, when issued by a MAC, be issued in accordance with the LCD process. The current LCD development and implementation process is set forth in agency guidance. Section 1869(f)(2)(B) of the Act defines an LCD as a determination by a MAC under part A or part B, as applicable, respecting whether or not a particular item or service is covered on a MAC jurisdiction-wide basis under such parts, in accordance with section 1862(a)(1)(A) of the Act.

While the LCD development process is not enumerated in statute, CMS' Internet-Only Manual 100–08, Medicare Program Integrity Manual, Chapter 13, lays out the process for establishing LCDs. The manual outlines the steps in LCD development including: The posting of a draft LCD with a public comment period, a public meeting and presentation to an expert advisory committee, and, after consideration of comments, issuance of a final LCD followed by at least a 45-day notice period prior to the policy becoming effective. This LCD development process has been used by the MACs since 2003.

In addition to addressing LCD development and implementation, section 1834A(g)(1)(A) of the Act states that the processes governing the appeal and review of LCDs for CDLTs must be consistent with the general LCD appeal and review rules that we have issued at 42 CFR part 426. The LCD appeals process allows an ''aggrieved party'' to challenge an LCD or LCD provisions in effect at the time of the challenge. An aggrieved party is defined as a Medicare beneficiary, or the estate of a Medicare beneficiary, who is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan, or in another Medicare managed care plan), and is in need of coverage for an item or service that would be denied by an LCD, as documented by the beneficiary's treating physician, regardless of whether the service has been received.

Section 1834A(g)(1)(B) of the Act provides that the CDLT-related LCD provisions referenced in section 1834A(g) do not apply to the NCD process (as defined in section 1869(f)(1)(B) of the Act). The NCD process is outlined in section 1862(l) of the Act and further articulated in the August 7, 2013 **Federal Register** (78 FR 48164).

Section 1834A(g)(1)(C) of the Act specifies that the provisions pertaining to the LCD process for CDLTs, including appeals, shall apply to coverage policies issued on or after January 1, 2015.

Beyond specifying how the Medicare LCD process will relate to CDLTs, 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 have authority to establish LCDs and process claims for CDLTs. We believe the statute authorizes us to reduce the number of MACs issuing LCDs for CDLTs, which would result in fewer contractors issuing policies for larger geographic areas. If we were to exercise only the authority to reduce the number of MACs issuing LCDs for CDLTs, such a change could likely be finalized within the next 2 to 4 years. However, reducing the number of MACs processing claims for CDLTs would involve significantly more complex programmatic and operational issues. For instance, the consolidation of Medicare claims processing for CDLTs would require complex changes to Medicare's computer systems. Thus, such a transition could take several years to implement. To be consistent with the statute, we believe the agency would need to conduct various analyses to determine the feasibility and program desirability of moving forward with consolidating the number of MACs making coverage policies and processing claims for CDLTs. We believe that the medical complexity of many tests and the volume of tests overall would require serious consideration of several factors before the agency could decide whether to consolidate all MAC CDLT processes into 1–4 MACs. For instance, if only coverage policies were to be developed by a smaller number of MACs, issues could arise for the other MACs that would need to implement policies, edit claims and defend LCD policies that they did not author. Moreover, the same policy may be implemented differently among MACs based on the ability of their individual claims processing systems to support certain types of editing and/or their differing assessment of risk and technical solutions. Finally, if both LCD development and claims processing were combined and consolidated, we would need to consider that the MAC processing the laboratory claim (in most cases) would not be the same MAC that processes the claim of the ordering physician. This could complicate the development of a full profile of the ordering physician's practice patterns for quality and medical necessity assessment purposes.

The timing for implementation of section 1834A(g)(2) of the Act (if we chose to exercise this authority) would be largely dependent on the time it would take the agency to develop new MAC statements of work, modify existing or develop new MAC contracts, and address the policy, information technology and technical aspects of the claims processing environment including the potential development of a new system. Implementing the fullest scope of the authority granted by this section, by which we would reduce both the number of MACs writing coverage policies for CDLT services and the number of MACs processing CDLT claims, could take at least 5 to 6 years and involve considerable costs. For example, to establish centralized LCDs for all CDLTs would probably involve an initial build-up and then a steady-state investment of several million dollars per year. To create regional lab test claims processors (in addition to development of LCDs) would involve higher set-up costs, and some steady-state costs.

We received 27 comments on these proposals. Of those comments, two commenters were in favor of consolidating both LCD development and claims processing for CDLTs. Five commenters were in favor of only MAC LCD consolidation for CDLTs. Of those five comments, four commenters said we may want to consider having MACs consolidate their LCDs for CDLTs but also raised concerns about such consolidation. Seven commenters were not in favor of having the MACs consolidate their LCDs for CDLTs. In regard to designating 1–4 MACs to

process CDLT claims, 3 commenters were in favor and 11 commenters were not in favor of consolidating claims processing for CDLTs.

A discussion of the comments we received on the benefits and risks of implementing the various scenarios authorized by this section of the statute, and our response to those comments, appears below.

a. Claims Processing Consolidation

Comments: Several commenters stated that they believe working with a single MAC to process all claims was preferred because of the increased paperwork and reporting burden associated with submitting claims to more than one MAC. These same commenters stated that the disadvantages of having a MAC process only CDLT claims would far outweigh the benefits; therefore, they were strongly opposed to designating more than one MAC to conduct claims processing.

Two commenters indicated that consolidating claims processing functions under 1–4 MACs may be problematic unless consolidation of claims processing functions applies only to independent labs. One commenter offered an alternative of using the Master Edit File to address CMS' concerns about the complexities of consolidating CDLT claims processing. This file, designed to function similarly to the Part B Drug Crosswalk Pricing file and the National Correct Coding Initiative edit file, could standardize processing across the MACs. Tools such as the Integrated Data Repository could also facilitate the necessary data analysis and payment review processes being performed at a single contractor.

b. LCD Consolidation

Comments: Several commenters recommended that CMS move to a system that consolidates the MACs for the purpose of administering coverage determinations for laboratory tests. The commenters varied on the total number of MACs CMS should use for CDLT coverage policies.

Two commenters indicated that CMS should consider designating a single contractor. One of these commenters believes a single contractor should be designated that has expertise in laboratory and precision medicine with the responsibility for coverage determinations for such tests. The commenter believes it would be difficult as well as inefficient for each MAC to develop this substantial and specialized expertise in laboratory medicine. The other commenter disagreed that it would take years to implement a national LCD process, and provided some suggestions on the LCD development process so that all MACs could release CDLT LCDs at the same time.

Four commenters indicated that if CMS were to move forward with fewer MACs developing LCDs it may put some MACs in a position of having to defend and/or abide by LCDs they did not develop. This could also create regional differences in how the same LCD would be enforced because a MAC's claims processing systems and editing capabilities differ.

Response: We appreciate the thoughtful comments on whether CMS should consolidate the MACs for the purpose of developing coverage policies and processing claims for CDLTs. Careful consideration will be given to the input from stakeholders as we consider whether to downsize the number of MACs developing LCDs and/or processing claims for CDLTs. In the interim, MACs should continue to develop and implement CDLT-related LCDs in accordance with the guidance set forth in Chapter 13 of the Medicare Program Integrity Manual and process Medicare claims for payment of CDLTs in the same manner it always has until further notice.

J. Other Provisions

1. Advisory Panel on Clinical Diagnostic Laboratory Tests

Section 1834A(f) of the Act sets out several requirements for input from clinicians and technical experts on issues related to CDLTs. 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. This advisory panel must be composed of an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics, in issues related to CDLTs, which may include the development, validation, performance, and application of such tests.

Section 1834A(f)(1)(A) of the Act provides that the advisory panel will generally provide input on the establishment of payment rates for new CDLTs, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test and the factors used in determining coverage and payment processes for new CDLTs. Section 1834A(f)(1)(B) of the Act provides that the panel will provide recommendations to the Secretary under section 1834A of the Act. Section 1834A(f)(2) of the Act mandates that the panel comply with the requirements of the Federal Advisory Committee Act (5 U.S.C. App.) (FACA). We proposed to add § 414.506(e) to codify the establishment of the Advisory Panel on CDLTs.

In the October 27, 2014 **Federal Register** (79 FR 63919), we announced the Advisory Panel on CDLTs. On April 16, 2015, we established the charter for the Panel. (See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/PAMA-Tab-F-1635-N.pdf*). As indicated in the charter, meetings will be held up to 4 times a year. Meetings will be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated in accordance with the Government in the Sunshine Act of 1976 (5 U.S.C. 552b(c)) and FACA. Notice of all meetings will be published in the **Federal Register** as required by applicable laws and Departmental regulations. Meetings will be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations. Additionally, in the August 7, 2015 **Federal Register** (80 FR 47491), we announced membership appointments to the Panel along with the first meeting date for the Panel. As we do with the Advisory Panel on Hospital Outpatient Payment (see *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*), we will make the Advisory Panel on CDLT's recommendations publicly available on the CMS Web site shortly after the panel's meeting. The first meeting of the panel was held at CMS on August 26, 2015. Information regarding the Panel is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Many commenters appreciated that Congress required the Secretary to establish the Advisory Panel to provide input on the many important issues related to clinical diagnostic laboratory testing and rate setting, and encouraged CMS to make use of the expertise on the Advisory Panel prior to setting payment rates and implementing the final rule.

In addition, a commenter noted that much of the discussion during the

Advisory Panel's meetings on August 26, 2015, and October 19, 2015, focused on specific codes that are being considered for payment on the CLFS in CY 2016, and suggested that the Advisory Panel be used to provide clinical and technical expertise on a wide range of clinical laboratory tests.

Response: We thank the commenters for their support of the Advisory Panel. We agree the Advisory Panel provides valuable expertise and we intend to utilize its input to the extent possible.

Comment: Several commenters suggested that subject matter experts be invited to participate on the Advisory Panel to discuss sub-specialty issues when the Advisory Panel lacks a subject matter expert on a specific issue being discussed.

Response: We appreciate the suggestion and will take it into consideration for future meetings.

Comment: A commenter requested that CMS follow more closely the recommendations of the Advisory Panel so that CMS actively engages in an open, transparent, and public decision-making process.

Response: We agree that the decision-making process should be as open and transparent as possible, and we will continue to consider all recommendations of the Advisory Panel in the decision-making process. We note that the Advisory Panel's meetings are open to the public in accordance with FACA requirements, and information related to the Advisory Panel (agenda, recommendations, etc.) are posted on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

Comment: Some commenters requested a mechanism for stakeholders to request that specific topics be added to the Advisory Panel's agenda in advance of scheduled meetings.

Response: Stakeholders who wish to request that an item be added to the Advisory Panel's meeting agenda should email their request to *CDLTPanel@cms.hhs.gov.*

Comment: Some commenters recommended adding Advisory Panel members from community-based laboratories to ensure that panel members understand how community-based clinical laboratories operate and the costs associated with providing testing services in a diversity of settings. Other commenters recommended adding panelists that run clinical laboratories, or have recent direct experience in the clinical laboratory industry and knowledge of how policies can be operationalized by clinical laboratories. Another commenter urged CMS to utilize the Advisory Panel to augment the subject matter expertise of MACs on coverage matters.

Response: We appreciate the suggestions and will consider these recommendations when a position on the Advisory Panel becomes available. The 15 Advisory Panel members have extensive expertise in issues related to clinical diagnostic laboratory tests and include representatives of clinical laboratories, molecular pathologists, clinical laboratory researchers, and individuals with expertise in clinical laboratory science or economics of clinical laboratory services. All Advisory Panel members have direct personal experience with clinical laboratory tests and services, and were selected to serve a 3-year term based on their leadership credentials, quality of their clinical laboratory experience, geographic and demographic factors, and the projected needs of the Advisory Panel.

Comment: Some commenters stated that although FACA requires only 15 days advance notice of meetings, CMS should provide at least 30 days notice to allow medical professionals time to plan travel and adjust their schedules to attend. Commenters also requested that CMS explore options to allow public comment via teleconference or webinar so stakeholders could actively participate in the process to address scheduling and cost issues associated with in-person attendance.

Response: We understand that 15 days as required by FACA may not be adequate time for all interested persons to make scheduling and travel arrangements to attend an Advisory Panel meeting. We will strive to provide additional notice whenever possible. Participants are able to call in and live stream the Advisory Panel meetings and we will consider allowing public comments to be provided via these mechanisms as well.

2. Exemption From Administrative and Judicial Review

Section 1834A(h)(1) of the Act states there shall be no administrative or judicial review under sections 1869 and 1878 of the Act, or otherwise, of the establishment of payment amounts under section 1834A of the Act. We proposed to codify this provision in § 414.507(e).

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Several commenters stated that there are likely to be errors in the data submitted, especially in the initial data reporting period, and since there is no opportunity for administrative or judicial review, they believe rates may be set for a three-year period based on incorrect information. While acknowledging that the law precludes administrative and judicial review of payment amounts, the commenters requested that CMS establish a process to accept requests for review of proposed rates, and noted that this is done in the Physician Fee Schedule and the Hospital Outpatient Prospective Payment System.

Response: We understand there are concerns regarding the accuracy of the data submitted, particularly for the initial data reporting period. As discussed in section II.F of this final rule, we plan to establish a process for public review of the CLFS rates, that is, the weighted median private payor rates, before they are finalized. We intend to make available to the public a list of test codes and the CLFS rates associated with those codes, which is the same CLFS information we currently make available to the public. We stated that, while we will not release any information that identifies a payor or a laboratory, we will also make available to the public a file that includes aggregate-level private payor rate and volume data for each test code (for example, the unweighted median private payor rate; the total, median and or mean volume; number of laboratories reporting), and that this information will be released to the public before the final rates are published to better enable the public to comment about the general accuracy of the reported data. We also noted that we are exploring whether we can make available the raw data that is reported to us (that is, is the actual, un-aggregated data that is reported as applicable information for an applicable laboratory) in order to provide even more granular data for the public's review, but we would not provide aggregate or raw data for tests we consider to be uncommon or that we know to be provided by a single laboratory (such as for new ADLTs) to avoid potential disclosure of the prices charged or payments made to an individual laboratory. We believe this process could provide even more transparency for the public to review and comment on the new CLFS payment rates before they are made effective. Details of this process, if established, will be provided in subregulatory guidance.

3. Sample Collection Fee

Section 1834A(b)(5) of the Act increases by $2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a sample

collected from an individual in a SNF or by a laboratory on behalf of a HHA. We stated in the proposed rule that this provision was implemented via Medicare Change Request (CR) transmittal effective December 1, 2014 (Transmittal #R3056CP; CR #8837) and that we proposed to reflect this policy in § 414.507(f). However, Transmittal #R3056CP; CR #8837 was effective April 1, 2014 and implemented December 1, 2014. Therefore, we are revising § 414.507(f) to reflect the effective date for this provision of April 1, 2014.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Some commenters believed that our interpretation of the statute has prevented laboratories from receiving the sample collection fee increase if they provide services to patients designated by physicians as homebound, or if they provide services to patients that go back and forth within a shared SNF/NF facility. They noted that we allow HHAs to collect the fee but not to bill Part B for the specimen collection, even though SNFs are allowed to bill Part B for the specimen collection fees. The commenters proposed that we allow laboratories that provide specimen collection services to receive the increase in the fee by billing using place of service codes for SNFs, NFs, and for homebound patients in a private residence.

Response: The statute states that the sample collection fee shall be increased for samples collected from an individual in a SNF or by a laboratory on behalf of a HHA. The authority does not extend to sample specimens collected from patients designated as homebound, even if place of service codes were utilized.

III. Collection of Information Requirements

As stated in section 1834A(h)(2) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the information collection requirements contained in section 1834A of the Act. Consequently, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget.

IV. Waiver of Proposed Notice and Comment Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA). The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. However, this procedure can be waived if the Secretary finds, for good cause, that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefor in the rule.

We are finalizing the CMP amounts adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114–74) (the 2015 Act) without public notice and comment. The 2015 Act is very prescriptive in the formula that we must apply in adjusting the civil monetary penalties, leaving us no flexibility to exercise discretion in calculating the inflation adjustments to the CMP amounts. Therefore, we find good cause to waive notice and comment procedures as unnecessary.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to establish a methodology for implementing the requirements in section 1834A of the Act, including a process for data collection and reporting, a weighted median calculation methodology, and requirements for how and to whom these policies would apply.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule is an economically significant rule because we believe that the changes to how CLFS payment rates will be developed will overall decrease payments to entities paid under the CLFS. We estimate that this final rule is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of the rulemaking.

C. Limitations of Our Analysis

Our analysis presents the projected effects of our implementation of new section 1834A of the Act. As described earlier in this final rule, a part of this rule describes a schedule and process for collecting the private payor rate information of certain laboratories. Until such time that these data are available, we are limited in our ability to estimate effects of our CLFS payment policies under different scenarios.

D. Anticipated Effects

1. Effects on Entities Paid Under the CLFS

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most of the entities paid under the CLFS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small

entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year).

For purposes of the RFA, we estimate 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 $32.5 million or less in any 1 year: $32.5 million for medical laboratories and $11 million for doctors. Individuals and states are not included in the definition of a small entity. Using the codes for laboratories in the North American Industry Classification System (NAICS), more than 90 percent of medical laboratories would be considered small businesses. This final 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.

In the proposed rule (80 FR 59391through 59394), we proposed to define applicable laboratory at the TIN level. Approximately 68,000 unique TIN entities are enrolled in the Medicare program 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 a skilled nursing facility. In section II.A. of this final rule, we discussed that after considering commenters' suggestions, we have revised the proposal and, as a final policy, we are defining applicable laboratory at the NPI level. Approximately 266,000 unique NPI-level entities are enrolled in the Medicare program as a laboratory and paid under the CLFS. Of these unique NPI-level entities, 93 percent are enrolled as a physician office laboratory, 1 percent are enrolled as independent laboratories while the remaining 6 percent are attributed to other types of laboratories such as those operating within a rural health clinic or a skilled nursing facility. Given that well over 90 percent of Medicare enrolled laboratories paid under the CLFS are physician-owned laboratories, we estimate the majority of Medicare-enrolled laboratories would meet the SBA definition of a small business. While the NPI-level entity will be the applicable laboratory, the TIN-level entity will be responsible for reporting applicable information for all the NPIs in its organization that are applicable laboratories. We believe that reporting at the TIN level will require reporting from fewer entities and will, therefore, be less burdensome to all types of applicable laboratories—that is independent laboratories, physician office laboratories, and hospital outreach laboratories—than would requiring applicable laboratories to report.

As discussed in section II.B of this final rule, the applicable information required to be reported to CMS includes each private payor rate, the associated volume of tests performed corresponding to each private payor rate, and the specific HCPCS code associated with the test. We specifically intended to minimize the reporting burden by only requiring the minimum information necessary to enable us to set CLFS payment rates. We are not requiring (or permitting) individual claims to be reported because claims include more information than we need to set payment rates (and also raises concerns about reporting personally identifiable information). We believe that each of these policies, which are finalized in this rule, will substantially reduce the reporting burden for reporting entities in general and small businesses in particular.

Given that we have never collected information about private payor rates for tests from laboratories, we do not have the specific payment amounts from the weighted median of private payor rates that will result from implementation of section 1834A of the Act. For this reason, it is not possible to determine an impact at the level of the individual laboratory or physician office laboratory much less distinctly for small and other businesses. While the information provided elsewhere in this impact statement provide the aggregate level of changes in payments, these estimates were done by comparing the differences in payment amounts for laboratory tests from private payers with the Medicare CLFS payment adjusted for changes expected to occur by CY 2018. While this methodology can be used to estimate an overall aggregate change in payment for services paid using the CLFS, the impact on any individual laboratory will depend on the mix of laboratory services provided by the individual laboratory or physician office.

A final regulation is generally deemed to have a significant impact on small businesses if the rule is estimated to have an impact greater than a 3 to 4 percentage change to their revenue. As discussed previously in this section, we estimate that most entities furnishing laboratory tests paid under the CLFS would be considered a small business. Therefore, we believe our accounting statement provides a reasonable representation of the impact of the changes to the CLFS on small businesses (see Table 14). As illustrated in Table 14, the effect on the Medicare program is expected to be $390 million less in Part B program payments for CLFS tests furnished in FY 2018. The 5-year impact is estimated to be $1.71 billion less and the 10-year impact is expected to result in $3.93 billion less in program payments. As discussed previously, overall, Medicare pays approximately $7 billion a year under the current CLFS for CDLTs. Using our estimated amount of changes in CLFS spending, we estimate an overall percentage reduction in revenue of approximately −5.6 percent for FY 2018 (−$390 million/$7 billion = −5.6 percent); a 5-year percentage reduction of about 4.9 percent (−$1.71 billion/$35 billion = −4.9 percent) and a 10-year percentage reduction of approximately 5.6 percent (−$3.93 billion/$70 billion = −5.61percent). As such, we estimate that the revisions to the CLFS as authorized by PAMA will have a significant impact on small businesses.

We note that the above estimates differ from the estimates indicated in the regulatory impact analysis section of the proposed rule. The difference is due to the move in implementation from January 1, 2017, to January 1, 2018. The move not only eliminated a year of potential savings but resulted in less future savings as another year of productivity adjustments will take effect and essentially narrow the gap between private payor rates and Medicare rates.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not have a significant impact on small rural hospitals because the majority of entities paid under the CLFS and affected by the policies are independent laboratories and physician offices. To the extent that rural hospitals own independent laboratories and to the extent that rural hospitals are paid under the CLFS, there could be a significant impact on those facilities. Since most payments for laboratory tests to hospitals are bundled in Medicare Severity Diagnosis Related Group payments under Part A, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of

small rural hospitals. We requested comment from small rural hospitals on (1) their relationships with independent clinical laboratories and (2) the potential impact of a reduction in CLFS payments on their revenues and profits. We received no comments.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately $146 million. This final rule does not contain mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have examined the CLFS provisions included in this final rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on state, local or tribal governments, preempt state law, or otherwise have a Federalism implication. While we have limited information about entities billing the CLFS with government ownership, the limited amount of information we currently have indicates that the number of those entities, as well as CLFS payment amounts associated with them, are minimal. Based on 2013 claims data, we received only 21,627 claims for CLFS services from a total of 50 state or local public health clinics (0.1 percent of total laboratories that billed under the CLFS). However, we note that this final rule will potentially affect payments to a substantial number of laboratory test suppliers, and some effects may be significant.

2. Effects on the Medicare and Medicaid Programs

Section 1834A of the Acts requires that the payment amount for tests on the CLFS, beginning January 1, 2017, be based on private payor rates. As discussed in the proposed rule (80 FR 59416), we estimated the effect on the Medicare program is expected to be $360 million less in program payments for CLFS tests furnished in FY 2017. However, as discussed in section II.D of this final rule, we are moving the implementation date of the private payor rate-based CLFS to January 1, 2018. As a result, we revised the estimated amount of change in CLFS spending to reflect the revised implementation date.

The effect on the Medicare program is expected to be $390 million less in program payments for CLFS tests furnished in FY 2018. We first established a baseline difference between Medicare CLFS payment rates and private payor rates based on a study by the Office of Inspector General, ''Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings'', OEI–07–11–00010, June 2013. The OIG study showed that Medicare paid between 18 and 30 percent more than other insurers for 20 high-volume and/or high-expenditure lab tests. We assumed the private payor rates to be approximately 20 percent lower than the Medicare CLFS payment rates for all tests paid under the CLFS in CY2010. We then accounted for the legislated 5 years of 1.75 percent cuts to laboratory payments, as required by section 1833(h)(2)(A)(iv)(II) of the Act, as well as 8 years of multi-factor productivity adjustments, as required by section 1833(h)(2)(A) of the Act, to establish a new baseline difference between private payor rates and Medicare CLFS payment rates of approximately 5.8 percent in 2018. The new baseline difference between Medicare CLFS payment rates and private payor rates (5.8 percent) results in an approximate savings to the Medicare program of $390 million in FY 2018. We projected the FY 2018 Medicare savings of $390 million forward by assuming a rate of growth proportional to the growth in the CLFS (that is approximately 8.2 percent annually over the projection window FY 2016 through FY 2025) after adjusting for additional productivity adjustments to determine a 10-year cost savings estimate (as illustrated in Table 14). We note that the 1-year move in implementation of this final rule reduces the 10-year estimated amount of change in CLFS spending by approximately $790 million. The effect on the Medicaid program is expected to be limited to payments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We note that section 6300.2 of the CMS State Medicaid Manual states that Medicaid reimbursement for CDLTs may not exceed the amount that Medicare recognizes for such tests.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: One commenter expressed concern that projected payment reductions for laboratories in 2017 and potential savings for Medicare surpasses the original goals for PAMA. For example, this commenter indicated that CMS projected the new laboratory payment rates to result in $360 million in payment reductions for laboratories in 2017 and potential savings for Medicare of over $5.14 billion over 10 years. The commenter believes these saving estimates are much greater than those released by the Congressional Budget Office (CBO) when PAMA was enacted. The commenters cite that CBO estimated savings of $100 million in 2017 and $2.5 billion over 10 years. The commenter recommended CMS make significant revisions before finalizing the proposed rule.

Response: We acknowledge a difference in payment projections released by CBO and CMS. We believe this difference is due to the following: (1) CBO estimates were based on an OIG [3] study that examined the top 25 Medicare laboratory test payments, whereas our estimates were based on all laboratory tests billed under the CLFS; (2) CBO estimates utilized 2014 Medicare claims data, whereas we used the 2010 OIG data analysis to establish a baseline difference in the payments between CLFS and the private payor rates; and (3) CBO provided payment projections from 2014 to 2024, whereas we provided payment projections from 2016 to 2025.

3. Cost of Data Collection and Reporting Activities

As discussed previously, the applicable information of applicable laboratories must be collected, and reporting entities will be required to report that information to CMS. Section II.E.1. addresses penalties for non-reporting. We believe there could be substantial costs associated with compliance with section 1834A. As we had only limited information upon which to develop a cost estimate for collecting and reporting applicable information, we did not propose an estimate of the cost of data collection and reporting. As discussed below, we provided an illustrative example of the potential magnitude of collecting and reporting applicable information under the revised private payor rate based CLFS.

As noted previously, the CLFS has grown from approximately 400 tests to over 1,300 tests. For the proposed rule, we were not able to ascertain how many private payors and private payor rates there are for each applicable laboratory, and therefore, provided a hypothetical

[3] HHS OIG Data Brief, Medicare Payment for Clinical Laboratory Tests in 2014: Baseline Data. *Office of Inspector General,* September 2015.

example to illustrate the number of records (with one record being the specific HCPCS code, the associated private payor rate, and volume) that a reporting entity could be required to report for an applicable laboratory under the proposed rule. If an applicable laboratory had 30 different private payor rates for a given test and it received private payor payment for each test on the CLFS, the reporting entity would be reporting 39,000 records (1,300 tests × 30) and 117,000 data points (one data point each for the HCPCS code and its associated private payor rate and volume). We explained that this example is hypothetical and illustrative only but demonstrates the potential volume of information a reporting entity may be required to report for a given applicable laboratory. It seems likely that most applicable laboratories will not have private payor rates for each test on the CLFS and that a small number of tests will have the highest volume and more associated private payor rates. To the extent that a laboratory receives private payor payment for fewer than the 1,300 tests paid under the CLFS, the data collection and reporting burden will be less (and accordingly the 1,300 multiplier will be less) than in the above example. To the extent a private payor has more or less than 30 private payor rates, the multiplier will differ from 30 in the above example.

To better understand the projected reporting, recordkeeping or other compliance requirements, we specifically requested comments on the following questions concerning applicable laboratories:

- 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 (for example, 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 (for example, calendar year or other 12 month reporting period)?
- Is the information that laboratories are required to report readily available in the applicable laboratories' record systems?
- 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 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?

We believed that these items would be important factors to consider before projecting data reporting and record-keeping requirements. A discussion of the comments we received on this topic and our responses to those comment, appears below.

Comment: We received two comments on these items. One commenter expressed concern regarding the impact of anticipated administration burden. For example, the commenter indicated that they would need to make changes to information technology (IT) systems in order to collect, validate and report applicable data to CMS. Another commenter indicated that data reporting provisions in the proposed rule would require significant IT systems changes that could cost $300,000–$600,000. Additionally, the commenter estimated that a manual payment remittance process would cost $1.2 million for a 6 month data collection period and would require hiring 5 full-time equivalent staff at approximately $80,000 in annual salaries, wages and benefits.

Response: As noted above, the CLFS has grown from approximately 400 tests to over 1,300 tests. We assume that none of these tests are only furnished to Medicare beneficiaries or are only charged to Medicare, therefore, we expect applicable information (that is, private payor rates and associated volume) to be reported by applicable laboratories on nearly all of these tests. As discussed in the RIA, approximately 266,000 unique NPI-level entities are enrolled in the Medicare program as a laboratory and paid under the CLFS. Of these unique NPI-level entities, 93 percent (approximately 247,000) are enrolled as a physician office laboratory, 1 percent (approximately 2,700) are enrolled as independent laboratories while the remaining 6 percent (approximately 16,000) are attributed to other types of laboratories such as those operating within a rural health clinic or a skilled nursing facility. Given our estimate that the low expenditure threshold will exclude approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories from having to report applicable information, approximately 12,400 physician office laboratories (247,000 × .05) would be an applicable laboratory and approximately 1,200 independent laboratories (2,700 × .45) would an applicable laboratory for an estimated total of approximately 13,600 applicable laboratories.

According to the National Association of Insurance Commissioners, there were 859 domestic insurers in the United States in 2015.[4] While it is difficult to ascertain how many private payors and private payor rates there are for each applicable laboratory, we understand from an inquiry to an association representing laboratories that each applicable laboratory will bill approximately 1,500 different private insurers. We note that this estimate presumes a finite number of different private payors that may have an agreement with different entities, therefore significantly increasing the total amount of different private insurers. For example, a private insurer may have separate agreements with Federal, State, and County governments, as well as different agreements with various private sector companies. In our estimate, these different agreements are counted as separate private insurers. Some laboratories may bill more or fewer private payors, but we believe this is a reasonable number based on the information furnished to us. For simplicity, we also assume that each applicable laboratory is paid a single private payor rate by each private payor for each laboratory test during a data collection period.

Additionally, although we expect applicable information (that is, private payor rates and associated volume) to be reported by applicable laboratories on nearly all of the approximately 1300 tests on the CLFS, it seems likely that most applicable laboratories will not have private payor rates for each test on the CLFS and that a small number of tests will have the highest volume and more associated private payor rates. For instance, based on 2013 Medicare claims data, 25 tests accounted for over 85 percent of the total allowed services paid on the CLFS. Assuming that all of the estimated applicable laboratories (approximately 13,600) would report a single private payor rate for each of the most common 25 laboratory tests paid on the CLFS, we estimate there would be approximately 37,500 data points reported per applicable laboratory (25 laboratory test rates × 1,500 private payors) and approximately 510 million total data points reported for all applicable laboratories (13,600 estimated applicable laboratories × estimated 37,500 data points per applicable laboratory). As these 510 million data points are for the 25

[4] National Association of Insurance Commissioners, 2015 Insurance Department Resources Uses Report, Volume 1, page 27.

laboratory tests that account for 85 percent of the volume of tests paid on the CLFS, we would expect the total number of data points to be closer to 600 million (510 million/0.85) when accounting for the remaining laboratory tests paid under the CLFS. We believe the most time consuming of the activities related to data collection would be done by an office staff worker such as an Office Clerk (Occupational Category 49–9061 according to the Bureau of Labor Statistics earning and average hourly wage of $15.33). We believe this wage rate would not include benefits so there would be an additional cost assuming benefits.[5] However, it is very difficult to estimate the number of hours this would require so we are unfortunately unable to come up with a cost estimate of this burden to include in the RIA. In addition, and we acknowledge that there is a high degree of uncertainty around our analysis as a result of the dearth of available data on which to estimate costs.

Additionally, we recognize that requirements set forth by section 1834A of the Act may necessitate changes to IT systems and other administrative changes for laboratories to implement the reporting requirements of section 1834A of the Act. One commenter indicated that IT systems changes resulting from the data collection and reporting requirements could cost $300,000 and as much as $600,000 to implement. We presume that the majority of applicable laboratories would have IT systems and would not need to rely extensively on a manual payment remittance process. Although the information we received from the comments regarding the cost of IT changes was insightful, it was insufficient to develop a cost estimate for data collection and reporting activities for the entire laboratory industry.

E. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding sections of this final rule provide descriptions of the statutory provisions that are addressed, identify policies where the statute recognizes the Secretary's discretion, present the rationale for our policies and, where relevant, alternatives that were considered.

In developing this final rule, we considered numerous alternatives to the final policies. Key areas where we considered alternatives include the organizational level associated with an applicable laboratory, authority to develop a low volume or low expenditure threshold to reduce reporting burden for small businesses, whether to include coinsurance amounts as part of the applicable information, the definition of the initial reporting period for ADLTs, and how to set rates for CDLTs for which the agency receives no applicable information. Below, we discuss alternative policies considered. We recognize that all of the alternatives considered could have a potential impact on the cost or savings under the CLFS. However, we do not have any private payor rate information with which to price these alternative approaches.

1. Definition of Applicable Laboratory—TIN vs. NPI

As discussed previously in this section, we proposed to define an applicable laboratory at the TIN level rather than the NPI level because we believed that reporting applicable information would be less burdensome for applicable laboratories. However, as discussed in detail in section II.A of this final rule, in response to public comments, we revised our proposal and, as a final policy adopted in this final rule, we are defining applicable laboratory at the NPI level while maintaining that the TIN-level entity will be the reporting entity. We believe that having the TIN-level entity report applicable information for all of the NPI-level entities in its organization that are applicable laboratories will not affect or diminish the quality of the applicable information reported and should produce the same applicable information as reporting individually at the NPI level.

2. Authority To Develop a Low Volume or Low Expenditure Threshold To Reduce Reporting Burden for Small Businesses

We proposed to exercise our authority to develop a low expenditure threshold to exclude small businesses from having to report applicable information. Specifically, we proposed that any entity that would otherwise be an applicable laboratory, but that received less than $50,000 in Medicare revenues under sections 1834A and 1833(h) of the Act (the CLFS) for tests furnished during a data collection period, would not be an applicable laboratory. We considered the alternative of not proposing a low volume or low expenditure threshold which would require all entities meeting the definition of applicable laboratory to report applicable information to us. However, by proposing a low expenditure threshold we were able to substantially reduce the number of entities required to report applicable information to us (94 percent of physician office laboratories and 52 percent of independent laboratories would not be required to report applicable information) while retaining a high percentage of Medicare utilization (that is, 96 percent of CLFS spending on physician office laboratories and more than 99 percent of CLFS spending on independent laboratories) from applicable laboratories that would be required to report. We did not pursue a low volume threshold because we believed it could potentially exclude laboratories that perform a low volume of very expensive tests from reporting applicable information.

As discussed section II.A of this final rule, we are revising the low expenditure threshold consistent with defining an applicable laboratory at the NPI level rather than the TIN level. We are also revising the low expenditure threshold consistent with our decision in this final rule to change the data collection period from 12 months to 6 months, which will also reduce the reporting burden for reporting entities (see detailed discussion in section II.D. of this final rule). With these changes, the low expenditure threshold is reduced from $50,000 in the proposed rule to $12,500 in this final rule. As we found for the proposed rule, the application of the low expenditure threshold will significantly reduce the number of laboratories qualifying as applicable laboratories and substantially reduce the reporting burden for small businesses. We estimate that the low expenditure threshold of $12,500 adopted in this final rule will exclude approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories from having to report applicable information, while retaining a high percentage of Medicare utilization (that is, approximately 92 percent of CLFS spending on physician office laboratories and approximately 99 percent of CLFS spending on independent laboratories). Additionally, as discussed in section II.A., for a single laboratory that offers and furnishes an ADLT, the $12,500 threshold will not apply with respect to the ADLT. This means, if the laboratory otherwise meets the definition of applicable laboratory, whether or not it meets the low expenditure threshold, it will be

[5] United States Department of Labor, Bureau of Labor Statistics, Occupational and Employment Wages, May, 2015, 43–9061 Office Clerks, General. *http://www.bls.gov/oes/current/oes439061.htm.*

considered an applicable laboratory with respect to the ADLT it offers and furnishes, and must report applicable information for its ADLT. If it does not meet the threshold, it will not be considered an applicable laboratory with respect to all the other CDLTs it furnishes.

3. Definition of New ADLT Initial Period

As explained in section II.D. of this final rule, section 1834A(d)(1)(A) of the Act requires an ''initial period'' of three quarters during which payment for new ADLTs is based on the actual list charge for the laboratory test. The statute does not specify when this initial period of three quarters is to begin. Section 1834A(d)(2) of the Act requires reporting of applicable information not later than the last day of the Q2 of the new ADLT initial period. These private payor rates will be used to determine the CLFS rate after the new ADLT initial period ends. We considered starting the new ADLT initial period on the day the new ADLT is first performed (which in most cases would be after a calendar quarter begins). However, as noted previously in this final rule, if we were to start the new ADLT initial period after the beginning of a calendar quarter, the 2nd quarter would also begin in the midst of a calendar quarter, requiring the laboratory to report applicable information from the middle of the calendar quarter rather than on a calendar quarter basis. Further, if a new ADLT initial period of three quarters would also end during a calendar quarter, the laboratory would start getting paid the weighted median rate in the middle of the calendar quarter rather at the beginning of a calendar quarter. This may be burdensome and confusing for laboratories. As such, we believe that the new ADLT initial period should start and end on the basis of a calendar quarter (for example, January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31) for consistency with how private payor rates will be reported and determined for CDLTs (on the basis of a calendar year which is four quarters aggregated) and how CLFS rates will be paid (also on the basis of a calendar year). As discussed in section II.D., we are revising the definition of new ADLT initial period in § 414.502 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 or ADLT status is granted by us.

4. Recoupment of Payment for New ADLTs

As discussed in section II.H.4. of this final rule, the statute specifies that if, after a new ADLT initial period, the Secretary determines the payment amount that was applicable during the initial period (the test's actual list charge) was greater than 130 percent of the payment amount that is applicable after such period (based on private payor rates), the Secretary shall recoup the difference between those payment amounts for tests furnished during the initial period. We proposed to recoup the entire amount of the difference between the actual list charge and the weighted median private payer rate. After consideration of public comments, we revised our proposed policy so that, for tests furnished during the new ADLT initial period, we will pay up to 130 percent of the weighted median private payor rate. That is, if the actual list charge is subsequently determined to be greater than 130 percent of the weighted median private payor rate, we will recoup the difference between the actual list charge and 130 percent of the weighted median private payer rate. As we currently do not have information upon which to develop a cost estimate for this final recoupment policy, we cannot estimate how this policy will impact future payments under the CLFS. We do not anticipate many laboratory tests will meet the criteria for being an ADLT, therefore, we do not expect this final recoupment policy will have a significant impact on total CLFS spending.

5. Medicare Payment for Tests Where No Applicable Information Is Reported

As discussed in section II.B of this final rule, in the event we do not receive applicable information for a laboratory test that is provided to a Medicare beneficiary, we will use crosswalking and gapfilling using the definitions in § 414.508(b)(1) and (2) to establish a payment rate on or after January 1, 2018, which will remain in effect until the year following the next data reporting period. This policy includes the situation where we receive no applicable information for tests that were previously priced using gapfilling or crosswalking or where we had previously priced a test using the weighted median methodology. If we receive no applicable information in a subsequent data reporting period, we will use crosswalking or gapfilling methodologies to establish the payment amount for the test. That is, if in a subsequent data reporting period, no applicable information is reported, we will reevaluate the basis for payment, of crosswalking or gapfilling, and the payment amount for the test.

In exploring what we would do if we receive no applicable information for a CDLT, we alternatively considered carrying over the current payment amount for a test under the current CLFS, the payment amount for a test (if one was available) using the weighted median methodology based on applicable information from the previous data reporting period, or the gapfilled or crosswalked payment amount. However, we did not adopt this approach because we believe carrying over previous payment rates would not reflect changes in costs or pricing for the test over time. As noted previously, we believe reconsidering payment rates for tests in these situations is consistent with the purpose of section 1834A of the Act, which requires us to periodically reconsider CLFS payment rates. In this final rule, we finalized our proposal for using crosswalking and gapfilling in the event we do not receive applicable information for a laboratory test.

6. Phased-In Payment Reduction

As discussed previously, we proposed to use the NLAs for purposes of applying the 10 percent reduction limit to CY 2017 payment amounts instead of using local fee schedule amounts. As previously explained, we believed the statute intends CLFS rates to be uniform nationwide, which is why it precludes any geographic adjustment. We proposed that if the weighted median calculated for a CDLT based on applicable information for CY 2017 would be more than 10 percent less than the CY 2016 NLA for that test, we would establish a Medicare payment amount for CY 2017 that is no less than 90 percent of the NLA (that is, no more than a 10 percent reduction). We proposed, for each of CY 2017 through 2022, we would apply the applicable percentage reduction limitation to the Medicare payment amount for the preceding year. The alternative would have been to apply the 10 percent reduction limitation to the lower of the NLA or the local fee schedule amount. This option would retain some of the features of the current payment methodology. Under this option, though, the Medicare payment amounts may be local fee schedule amounts, so there could continue to be regional variation in the Medicare payment amounts for CDLTs. We believe that Medicare infrequently pays less than the NLA and there would be significant burden for CMS to establish systems logic to establish transition payment

based on the lesser of the local fee schedule amount or the NLA. For this reason, and because we believe the statute intends there to be uniform national payment for CLFS services, we decided not to adopt this option.

As discussed in section II.D of this final rule, we are moving the implementation date of the private payor-based rates for the CLFS by one year, to January 1, 2018. Therefore we are making a corresponding change to the phase-in of payment reductions timetable to reflect the January 1, 2018 implementation date. We are codifying this change from the proposed rule in § 414.507(d) to indicate that a maximum payment reduction per year of 10 percent applies for years 2018 through 2020 and a maximum payment reduction per year of 15 percent applies for years 2021 through 2023.

We did not receive comments on the proposed rule regarding the phased-in reduction provisions. Therefore, we adopted our proposal for phased-in reduction, along with the above changes to the timetable, as final policy.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available on the Office of Management and Budget Web site at: *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), we have prepared an accounting statement in Table 14 to illustrate the impact of this final rule. The following table illustrates the estimated amount of change in CLFS spending under the policies set forth in this final rule.

TABLE 14—ACCOUNTING STATEMENT: ESTIMATED CLINICAL LABORATORY FEE SCHEDULE TRANSFERS FROM CY 2016 TO CY 2025 ASSOCIATED WITH THE FINALIZED CHANGES TO THE CLINICAL LABORATORY FEE SCHEDULE AS DESCRIBED IN SECTION 1834A OF THE ACT

Category	Estimates	Year dollar		
Transfers		Year dollar	Discount rate (percent)	Period covered
Federal Annualized Monetized Transfers (in millions)	−385 −374	2016 2016	3 7	2016–2025 2016–2025
From Whom to Whom	Federal Government to Entities that Receive Payments under the Medicare Clinical Laboratory Fee Schedule			

	Estimate (in millions)											5-year impact	10-year impact
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016–2020	2016–2025
FY Cash Impact (with MC)													
Part B:													
Benefits	.....	.....	.....	(520)	(930)	(820)	(760)	(830)	(570)	(380)	(410)	(2,270)	(5,220)
Premium													
Offset	.....	.....	.....	130	230	200	190	210	140	90	100	560	1,290
Total Part B	.....	.....	.....	(390)	(700)	(620)	(570)	(620)	(430)	(290)	(310)	(1,710)	(3,930)

G. Cost to the Federal Government

We are creating a data collection system, developing HCPCS codes for laboratory tests when needed, convening a FACA advisory committee to make recommendations on how to pay for new CDLTs including reviewing and making recommendations on applications for ADLTs, and undertaking other implementation activities. To implement these new standards, we anticipate initial federal start-up costs to be approximately $4 million per year. Once implemented, ongoing costs to collect data, review ADLTs, maintain data collection systems, and provide other upkeep and maintenance services will require an estimated $3 million annually in federal costs. We will continue to examine and seek comment on the potential impacts to both Medicare and Medicaid.

H. Conclusion

The changes we adopt in this final rule will affect suppliers who receive payment under the CLFS, primarily independent laboratories and physician offices. We are limited in our ability to determine the specific impact on different classes of suppliers at this time due to the data limitations noted earlier in this section. However, we anticipate that the updated information through this data collection process in combination with the exclusion of adjustments (geographic adjustment, budget neutrality adjustment, annual update, or other adjustment that may apply under other Medicare payment systems), as described in section 1834A(b)(4)(B) of the Act, will reduce aggregate payments made through the CLFS, and therefore, some supplier level payments. We note that this final rule includes changes that may affect different laboratory test suppliers differently, based on the types of tests they provide.

The previous analysis, together with the remainder of the preamble, provides a Regulatory Flexibility Analysis. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amend 42 CFR chapter IV as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 2. The heading for subpart G is revised to read as follows:

Subpart G—Payment for Clinical Diagnostic Laboratory Tests

§ 414.1 [Amended]

■ 3. Section 414.1 is amended by adding ''1834A—Improving policies for clinical diagnostic laboratory tests'' in numerical order.

■ 4. Section 414.500 is revised to read as follows:

§ 414.500 Basis and scope.

This subpart implements provisions of 1833(h)(8) of the Act and 1834A of the Act—procedures for determining the basis for, and amount of, payment for a clinical diagnostic laboratory test (CDLT).

■ 5. Section 414.502 is amended by adding the definitions of ''Actual list charge,'' ''Advanced diagnostic laboratory test (ADLT),'' ''Applicable information,'' ''Applicable laboratory,'' ''Data collection period,'' ''Data reporting period,'' ''National Provider Identifier,'' ''New advanced diagnostic laboratory test (ADLT),'' ''New ADLT initial period,'' ''New clinical diagnostic laboratory test (CDLT),'' ''Private payor,'' ''Private payor rate,'' ''Publicly available rate,'' ''Reporting entity,'' ''Single laboratory,'' ''Specific HCPCS code,'' ''Successor owner,'' and ''Taxpayer Identification Number (TIN)'' in alphabetical order to read as follows:

§ 414.502 Definitions.

* * * * *

Actual list charge means the publicly available rate on the first day the new advanced diagnostic laboratory test (ADLT) is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

Advanced diagnostic laboratory test (ADLT) means a clinical diagnostic laboratory test (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 single laboratory that designed the test or a successor owner of that laboratory, and meets one of the following criteria:

(1) The test—

(i) Is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;

(ii) When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a 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; and

(iv) May include other assays.

(2) The test is cleared or approved by the Food and Drug Administration.

Applicable information, with respect to each CDLT for a data collection period:

(1) Means—

(i) Each private payor rate for which final payment has been made during the data collection period;

(ii) The associated volume of tests performed corresponding to each private payor rate; and

(iii) The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test.

(2) Does not include information about a test for which payment is made on a capitated basis.

Applicable laboratory means an entity that:

(1) Is a laboratory, as defined in § 493.2 of this chapter;

(2) Bills Medicare Part B under its own National Provider Identifier (NPI);

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) Receives at least $12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this $12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

New advanced diagnostic laboratory test (ADLT) means an ADLT for which payment has not been made under the clinical laboratory fee schedule prior to January 1, 2018.

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.

New clinical diagnostic laboratory test (CDLT) means a CDLT that is assigned a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code, and that does not meet the definition of an ADLT.

* * * * *

Private payor means:

(1) A health insurance issuer, as defined in section 2791(b)(2) of the Public Health Service Act.

(2) A group health plan, as defined in section 2791(a)(1) of the Public Health Service Act.

(3) A Medicare Advantage plan under Medicare Part C, as defined in section 1859(b)(1) of the Act.

(4) A Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act.

Private payor rate, with respect to applicable information:

(1) Is the final amount that is 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.

(2) Includes any patient cost sharing amounts, if applicable.

(3) Does not include information about denied payments.

Publicly available rate means the lowest amount charged for an ADLT that is readily accessible in such forums as a company Web site, 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.

Reporting entity is the entity that reports tax-related information to the Internal Revenue Service (IRS) using its Taxpayer Identification Number (TIN) for its components that are applicable laboratories.

Single laboratory, for purposes of an ADLT, means:

(1) The laboratory, as defined in 42 CFR 493.2, which furnishes the test, and that may also design, offer, or sell the test; and

(2) The following entities, which may design, offer, or sell the test:

(i) The entity that owns the laboratory.

(ii) The entity that is owned by the laboratory.

Specific HCPCS code means a HCPCS code that does not include an unlisted CPT code, as established by the American Medical Association, or a Not Otherwise Classified (NOC) code, as established by the CMS HCPCS Workgroup.

* * * * *

Successor owner, for purposes of an ADLT, 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.* Transfer of title and property to another party.

(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. Transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

■ 6. Section 414.504 is added to read as follows:

§ 414.504 Data reporting requirements.

(a) In a data reporting period, a reporting entity must report applicable information for each CDLT furnished by its component applicable laboratories during the corresponding data collection period, as follows—

(1) For CDLTs that are not ADLTs, every 3 years beginning January 1, 2017.

(2) For ADLTs that are not new ADLTs, every year beginning January 1, 2017.

(3) For new ADLTs—

(i) Initially, no later than the last day of the second quarter of the new ADLT initial period; and

(ii) Thereafter, every year.

(b) Applicable information must be reported in the form and manner specified by CMS.

(c) A laboratory seeking new ADLT status for its test must, in its new ADLT application, attest to the actual list charge.

(d) To certify data integrity, the President, CEO, or CFO of a reporting entity, or an individual who has been delegated authority to sign for, and who reports directly to, such an officer, must sign the certification statement and be responsible for assuring that the data provided are accurate, complete, and truthful, and meets all the reporting parameters described in this section.

(e) If the Secretary determines that a reporting entity has failed to report applicable information for its applicable laboratories, or made a misrepresentation or omission in reporting applicable information for its applicable laboratories, the Secretary may apply a civil monetary penalty to a reporting entity in an amount of up to $10,000 per day, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114–74, November 2, 2015), for each failure to report or each such misrepresentation or omission. The provisions for civil monetary penalties that apply in general to the Medicare program under 42 U.S.C. 1320a–7b apply in the same manner to the laboratory data reporting process under this section.

(f) CMS or its contractors will not disclose applicable information reported to CMS under this section 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 the Congressional Budget Office, and the Medicare Payment Advisory Commission, to review the information, or as CMS determines is necessary to implement this subpart, such as disclosures to the HHS Office of Inspector General or the Department of Justice for oversight and enforcement activities.

(g) Applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory. For a single laboratory that offers and furnishes an ADLT that is not an applicable laboratory except with respect to its ADLTs, the applicable information of its CDLTs that are not ADLTs may not be reported.

■ 7. Section 414.506 is amended by revising the introductory text and paragraph (d)(1), and adding paragraphs (d)(3) and (4) and (e) to read as follows:

§ 414.506 Procedures for public consultation for payment for a new clinical diagnostic laboratory test.

For a new CDLT, CMS determines the basis for and amount of payment after performance of the following:

* * * * *

(d) * * *

(1) Proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, with an explanation of the reasons for each determination, the data on which the determinations are based, including recommendations from the Advisory Panel on CDLTs described in paragraph (e) of this section, and a request for written public comments within a specified time period on the proposed determination; and

* * * * *

(3) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section, CMS will provide an explanation of how it took into account the recommendations of the Advisory Panel on CDLTs described in paragraph (e) of this section.

(4) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section and § 414.509(b)(2)(i) and (iii) when CMS uses the gapfilling method described in § 414.508(b)(2), CMS will make available to the public an explanation of the payment rate for the test.

(e) CMS will consult with an expert outside advisory panel, called the Advisory Panel on CDLTs, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists researchers, and individuals with expertise in laboratory science or health economics, in issues related to CDLTs. This advisory panel will provide input on the establishment of payment rates under § 414.508 and provide recommendations to CMS under this subpart.

■ 8. Section 414.507 is added to read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

(a) *General rule.* Except as provided in paragraph (d) of this section, and §§ 414.508 and 414.522, the payment rate for a CDLT furnished on or after January 1, 2018, is equal to the weighted median for the test, as calculated under paragraph (b) of this section. Each payment rate will be in effect for a period of one calendar year for ADLTs and three calendar years for all other CDLTs, until the year following the next data collection period.

(b) *Methodology.* For each test under paragraph (a) of this section for which applicable information is reported, the weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory.

(c) The payment amounts established under this section are not subject to any adjustment, such as geographic, budget

neutrality, annual update, or other adjustment.

(d) *Phase-in of payment reductions.* For years 2018 through 2023, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

(1) 2018—10 percent of the national limitation amount for the test in 2017.

(2) 2019—10 percent of the payment rate established in 2018.

(3) 2020—10 percent of the payment rate established in 2019.

(4) 2021—15 percent of the payment rate established in 2020.

(5) 2022—15 percent of the payment rate established in 2021.

(6) 2023—15 percent of the payment rate established in 2022.

(e) There is no administrative or judicial review under sections 1869 and 1878 of the Social Security Act, or otherwise, of the payment rates established under this subpart.

(f) Effective April 1, 2014, the nominal fee that would otherwise apply for a sample collected from an individual in a Skilled Nursing Facility (SNF) or by a laboratory on behalf of a Home Health Agency (HHA) is $5.

(g) For a CDLT for which CMS receives no applicable information, payment is made based on the crosswalking or gapfilling methods described in § 414.508(b)(1) and (2).

(h) For ADLTs that are furnished between April 1, 2014 and December 31, 2017, payment is based on the crosswalking or gapfilling methods described in § 414.508(a).

■ 9. Section 414.508 is revised to read as follows:

§ 414.508 Payment for a new clinical diagnostic laboratory test.

(a) For a new CDLT that is assigned a new or substantially revised code between January 1, 2005 and December 31, 2017, CMS determines the payment amount based on either of the following:

(1) *Crosswalking.* Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the local fee schedule amounts and national limitation amount of the existing test.

(ii) Payment for the new CDLT code is made at the lesser of the local fee schedule amount or the national limitation amount.

(2) *Gapfilling.* Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the CDLT and routine discounts to charges;

(B) Resources required to perform the CDLT;

(C) Payment amounts determined by other payors; and

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(ii) In the second year, the test code is paid at the national limitation amount, which is the median of the contractor-specific amounts.

(iii) For a new CDLT for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the contractor-specific amounts will pay for the test appropriately. If CMS determines that the contractor-specific amounts will not pay for the test appropriately, CMS may crosswalk the test.

(b) For a new CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2018, CMS determines the payment amount based on either of the following until applicable information is available to establish a payment amount under the methodology described in § 414.507(b):

(1) *Crosswalking.* Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the payment amount established under § 414.507 of the comparable existing CDLT.

(ii) Payment for the new CDLT code is made at the payment amount established under § 414.507.

(2) *Gapfilling.* Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the test and routine discounts to charges;

(B) Resources required to perform the test;

(C) Payment amounts determined by other payors;

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and

(E) Other criteria CMS determines appropriate.

(ii) In the second year, the CDLT code is paid at the median of the Medicare Administrative Contractor-specific amounts.

■ 10. Section 414.509 is amended by revising the introductory text and paragraphs (b)(2)(i) through (v) to read as follows:

§ 414.509 Reconsideration of basis for and amount of payment for a new clinical diagnostic laboratory test.

For a new CDLT, the following reconsideration procedures apply:

* * * * *

(b) * * *

(2) * * *

(i) By April 30 of the year after CMS makes a determination under § 414.506(d)(2) or paragraph (a)(3) of this section that the basis for payment for a CDLT will be gapfilling, CMS posts interim Medicare Administrative Contractor-specific amounts on the CMS Web site.

(ii) For 60 days after CMS posts interim Medicare Administrative Contractor-specific amounts on the CMS Web site, CMS will receive public comments in written format regarding the interim Medicare Administrative Contractor-specific amounts.

(iii) After considering the public comments, CMS will post final Medicare Administrative Contractor-specific amounts on the CMS Web site.

(iv) For 30 days after CMS posts final Medicare Administrative Contractor-specific payment amounts on the CMS Web site, CMS will receive reconsideration requests in written format regarding whether CMS should reconsider the final Medicare Administrative Contractor-specific payment amount and median of the Medicare Administrative Contractor-specific payment amount for the CDLT.

(v) Considering reconsideration requests received, CMS may reconsider its determination of the amount of payment. As the result of a reconsideration, CMS may revise the median of the Medicare Administrative Contractor-specific payment amount for the CDLT.

* * * * *

■ 11. Section 414.522 is added to subpart G to read as follows:

§ 414.522 Payment for new advanced diagnostic laboratory tests.

(a) The payment rate for a new ADLT—

(1) During the new ADLT initial period, is equal to its actual list charge.

(2) Prior to the new ADLT initial period, is determined by the Medicare Administrative Contractor based on information provided by the laboratory

seeking new ADLT status for its laboratory test.

(b) After the new ADLT initial period, the payment rate for a new ADLT is equal to the weighted median established under the payment methodology described in § 414.507(b).

(c) If, after the new ADLT initial period, the actual list charge of a new ADLT is greater than 130 percent of the weighted median established under the payment methodology described in § 414.507, CMS will recoup the difference between the ADLT actual list charge and 130 percent of the weighted median.

(d) If CMS does not receive any applicable information for a new ADLT by the last day of the second quarter of the new ADLT initial period, the payment rate for the test is determined either by the gapfilling or crosswalking method as described in § 414.508(b)(1) and (2).

Dated: May 26, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 14, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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