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Part III

## Department of Health and Human Services

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Centers for Medicare & Medicaid Services

42 CFR Part 414

Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Proposed Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 414**

[CMS-1621-P]

RIN 0938-AS33

**Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System**

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would significantly revise the Medicare payment system for clinical diagnostic laboratory tests and would implement other changes required by section 216 of the Protecting Access to Medicare Act of 2014.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 24, 2015.

**ADDRESSES:** In commenting, please refer to file code CMS-1621-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1621-P, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1621-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert

H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:**

Marie Casey, (410) 786-7861 or Karen Reinhardt (410) 786-0189 for issues related to the local coverage determination process for clinical diagnostic laboratory tests.

Valerie Miller, (410) 786-4535 or Sarah Harding, (410) 786-4001 for all other issues.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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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 proposed 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. This statute requires extensive revisions to the Medicare payment, coding, and coverage requirements for CDLTs. In this proposed rule, we present our specific proposals for implementing the requirements of section 1834A of the Act.

#### 2. Summary of the Major Provisions of This Proposed Rule

Section 1834A of the Act significantly changes how CMS will set Medicare

payment rates for CDLTs, which are paid for on the CLFS. Applicable laboratories will be required to report to CMS certain information about the payment rates paid by private payors for each CDLT and the corresponding volumes of such tests furnished during a period of time specified by the Secretary of the Department of Health and Human Services (the Secretary). 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 advanced diagnostic laboratory tests (ADLTs). The most significant proposed policies in this proposed rule include the following (more detailed descriptions follow the bulleted list):

- The definition of “applicable laboratory” (the entities that must report applicable information).
- The definition of “applicable information” (the specific data that must be reported).
- The definition of an ADLT.
- Data collection and data reporting.
- The schedule for reporting applicable information to CMS.
- 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 designation of Medicare Administrative Contractors (MACs) for laboratory tests.

Under the authority of section 1834A(a)(2) of the Act, in section II.A of this proposed rule, we are proposing to define an “applicable laboratory” as a laboratory that receives more than 50 percent of its Medicare revenues from 42 CFR part 414, subparts G and B (that is, for services that are paid by Medicare under the CLFS and the Physician Fee Schedule (PFS)) in a data collection period. We also propose that if a laboratory receives less than \$50,000 in Medicare revenues in a data collection period from 42 CFR part 414, subpart G (that is, for services that are paid by Medicare on the CLFS), it would be excluded from the definition of an applicable laboratory. In addition, we are proposing to define applicable laboratories at the Taxpayer Identification Number (TIN) level rather than the National Provider Identifier (NPI) level.

The statute requires an applicable laboratory to report the following applicable information for each test on the CLFS it 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. As discussed in section II.B., we propose to use the term “private payor rate” in the context of applicable information, instead of “payment rate,” in order to minimize confusion because we typically use the term payment rate to generically refer to the amount paid under the CLFS. We propose that the private payor rate reflects the price for a test prior to application of any patient deductible and coinsurance amounts. We are also proposing that only applicable laboratories may report applicable information.

Section 1834A(d)(5) of the Act specifies criteria for defining an ADLT (discussed in section II.C.) and authorizes the Secretary to establish additional criteria. At this time, we are only proposing to apply the criteria specified in statute and are not proposing any additional criteria under the statutory authority conferred upon the Secretary.

In section II.D. of this proposed rule, for the initial data collection period, we propose that applicable laboratories must report applicable information to CMS for the period of July 1, 2015, through December 31, 2015. All subsequent data collection periods would cover a full calendar year (CY). Further, we are proposing that all applicable information, except for new ADLTs, would be due to CMS by March 31 of the year following the data collection period. We also propose that the applicable information for new ADLTs must be reported to CMS by the end of the second quarter of the new ADLT initial period.

We propose 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 (described in section II.E.). We propose to require all data to be certified by the President, Chief Executive Officer (CEO), or Chief Financial Officer (CFO) of a 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 (described in section II.F.).

We propose to use G codes, which are part of the Healthcare Common Procedure Coding System (HCPCS) coding system CMS uses 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.

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 propose that payment rates be determined by using crosswalking or gapfilling methods. These methods of determining payment are discussed in section II.H. of this proposed 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 this proposed rule, we are requesting public comment on the benefits and disadvantages of implementing this discretionary authority before making proposals on this topic. We are therefore making no proposals with regard to this topic at this time.

### 3. Summary of Costs and Benefits

In section V. of this proposed rule, we provide a regulatory impact analysis that, to the best of our ability, describes the expected impact of the proposals described in this proposed rule. The proposed policies, which would implement new section 1834A of the Act, include a process for collecting applicable information from applicable laboratories on the rates that are paid by private payors for CDLTs and their

associated volume. We note that, because such data are not yet available, we are limited in our ability to provide estimated impacts of the proposed payment policies under different scenarios.

### 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 this section, tests are paid the lesser of (1) the billed amount, (2) the fee schedule amount established by Medicare contractors, or (3) a National Limitation Amount (NLA), which is a percentage of the median of all the state and local fee schedules.

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 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, multiple existing test codes, or a portion of an existing test code on the CLFS. In such a case, CMS assigns the new test code the local fee schedule amount and the NLA of the existing test and pays 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, MACs establish local 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 employing a local amount on the basis of the median amount for the test code across all MACs. Once 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 \$8 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 faster 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.

Another complexity we must consider is the various types of laboratories that bill Medicare under the CLFS. Medicare-enrolled laboratories include a mix of national chains that furnish a large menu of tests, and small regional operations that may concentrate on a specific population, such as nursing home residents, or that have a small menu of tests. Physicians' offices also perform certain tests that are paid under 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 proposing to implement in this proposed rule.

Section 1834A(a)(1) of the Act requires reporting of private payor payment rates for CDLTs by applicable laboratories to establish Medicare payment rates for tests paid under the

CLFS. Specifically, each applicable laboratory must report to the Secretary, at a time specified by the Secretary and for a designated data collection period, applicable information for each CDLT the 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, 1833(h) (the statutory authorities under which CLFS payments are made), or 1848 (the authority under which PFS payments are made) of the Act. 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, the applicable laboratory must report each such payment rate and the volume for the test at each such rate. This 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 information reported by laboratories. 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 drug data collection process 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, this paragraph provides that, notwithstanding any other provision of law, information disclosed by a laboratory 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 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 (the date of enactment of PAMA), 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 market rate. 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 based on applicable information 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 (the date of enactment of PAMA), 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 utilize 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 CMS has 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) 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 Rule

In this section of the proposed rule, we outline our proposals on several topics, including, among others: The definitions of applicable laboratory and applicable information; the definitions of ADLTs and new ADLTs; the data collection period, and data reporting requirements; data integrity; confidentiality and public release of limited data; coding for certain CDLTs and ADLTs; payment methodology; and coverage.

### 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. This reporting begins January 1, 2016, and takes 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 consider what a laboratory is, and we incorporate 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 it is 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 (42 CFR 493.1). To be paid under Medicare, a laboratory must be CLIA-certified (42 CFR 410.32(d) and part 493). Therefore, we believe it is 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 Social Security Act. Nevertheless, we welcome public comments on alternative definitions of a laboratory that may be appropriate for this purpose.

CLIA defines 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.

We believe the same policy is also appropriate for our purposes. In addition, the services of those facilities that only collect or prepare specimens or serve as a mailing service are not paid on the CLFS. We propose 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.

Under the revised payment system for CDLTs, an applicable laboratory is the entity that must report 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 propose 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 would indicate that if the entity is not itself a laboratory, it has at least one component that is a laboratory, as defined in § 493.2.

Whether the applicable laboratory is itself a laboratory or is an entity that has at least one component that is a laboratory, the applicable laboratory is the entity that would be reporting 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 propose that the TIN-level entity is the applicable laboratory.

Each component of the 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 (45 CFR 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 would indicate this in the 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 propose to define TIN and NPI in § 414.502 by referring to definitions already in the Code of Federal Regulations.

In making this proposal, we considered defining an applicable laboratory at the NPI level instead of the TIN level. Some stakeholders have indicated that because they bill Medicare by NPI and not TIN, the NPI is the most appropriate level for reporting applicable information to Medicare. However, 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. In industry meetings that occurred while developing this proposed rule, 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 believe defining an applicable laboratory by TIN rather than by NPI will result in the same applicable information being reported, just at a higher level, and will require less reporting, and therefore, would be less burdensome to applicable laboratories. In addition to potentially being less burdensome, we do 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 as reporting at a lower level. Therefore, we are proposing to define applicable laboratory by TIN rather than by NPI. However, we solicit public comments on this aspect of the applicable laboratory definition and on whether there are other possibly superior approaches to defining an applicable laboratory, including 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 believe this approach may be operationally less burdensome than submitting separate data files by TIN or NPI. We also do not believe that 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 yet 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. We welcome public comments on allowing a corporate entity with which multiple TINs are associated to report applicable information for all of its TINs, as we have described.

Next, we consider 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 would 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 are applying 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 OPPI), 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 not, but has at least one component that is. We propose 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 are proposing 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 are proposing 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 note that section 1834A(a)(1) of the Act only mandates reporting from entities meeting the definition of an applicable laboratory. We believe the purpose of only mandating applicable laboratories to report applicable information is to ensure that 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. 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, we believe the statute intends to limit reporting primarily to independent laboratories and physician offices (other than those that meet the low expenditure or low volume threshold, if established by the Secretary) and not include other entities (such as hospitals, or other health care providers) that do not receive the majority of their revenues from PFS or CLFS services. For this reason, we are proposing to prohibit any entity that does not meet the definition of applicable laboratory from reporting applicable information to CMS, which we would reflect in paragraph (g) of the data reporting requirements in § 414.504.

We expect 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 propose 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 expect 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. This requirement would be reflected in the definition of applicable laboratory in § 414.502.

Finally, we are proposing 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 are including that threshold in our proposed definition of applicable laboratory in § 414.502. We believe 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 expect 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. Although the statute uses the term “expenditure,” in this discussion, we 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. We do not believe that 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 estimate there are only 17 tests whose utilization is completely attributed to laboratories that would not be 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 believe this was the best information available to us for the purpose of determining a low expenditure threshold for this proposed rule. Therefore, we propose 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 are proposing 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 section II.D.1., we are proposing 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 are proposing to specify that, during the data collection period of July 1, 2015, through December 31, 2015, to be an applicable laboratory, an entity must receive 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.

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 propose to codify the low expenditure threshold requirement as part of the definition of applicable laboratory in § 414.502.

We are not proposing a low volume threshold at this time. Once we obtain applicable information under the new payment system, however, 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, an applicable laboratory means 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 is either itself a laboratory, as defined in § 493.2, or, if it is not itself a laboratory, has at least one component that is. In a data collection period, an applicable laboratory must receive, 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 receive, 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 propose to codify this definition of applicable laboratory in § 414.502.

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

Several terms and concepts in our proposed definition require explanation. First, we address 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. We believe it could be confusing to the public if we use the term “payment rate” as it relates 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 believe “private payor rate” could be used in the context of applicable information rather than payment rate. Therefore, hereafter, we refer to the private payor rate in regard to applicable information, and we do so even when we are referring to the

statutory language that specifically references payment rate. When we use the term “payment rate” hereafter, unless we indicate otherwise, we are referring to the Medicare payment amount under the CLFS. In our proposed definition of private payor rate, we attempt to be clear that we are limiting the term to its use in the definition of applicable information.

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 are proposing to incorporate that element into our proposed definition of private payor rate. To calculate a CLFS amount, we believe it is 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 we propose 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 CMS generally does not require a beneficiary to pay a deductible or coinsurance on CLFS services, we believe it is 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 are proposing 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 believe, are not meant to be exhaustive. 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 are proposing that the amount paid by a private payor for a CDLT must be the amount after all price concessions were applied.

We propose to codify the definition of private payor rate in § 414.502. Specifically, we propose that the private payor rate, with respect to 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 address 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)). Such term does not include a group health plan. We would incorporate 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 would incorporate 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 pursuant to and in accordance with a contract under section 1857. We would incorporate 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 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 would incorporate 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 propose 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. And, 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 are proposing 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 are proposing 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.

We will also 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 section II.G. of this proposed rule for discussion of coding), applicable laboratories will need to report a HCPCS code for each test that specifically identifies the test being reported. We are proposing 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. Therefore, to ensure that applicable laboratories do not report applicable information with a NOC code or an unlisted CPT code, we are also proposing 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.

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 are proposing 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 do not believe that 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.

### *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 proposed 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 we explain here how we interpret and incorporate 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). With regard to the meaning of “single laboratory,” we believe the statute intends to ensure that we grant ADLT status to the one laboratory that offers and furnishes in the particular test, to the exclusion of all other laboratories. The way we propose to ensure this is the case, is to require the laboratory to be a facility with a single CLIA certificate as described in § 493.43(a) and (b) because we believe, in most instances, the laboratory’s single CLIA certificate will 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.<sup>1</sup> We do not believe those exceptions would apply to most or all laboratories seeking ADLT status for a given test and, even if they did, we do not believe those particular exceptions would undermine our effort to identify the single laboratory. We request comment on the impact of using the CLIA certificate to designate a single laboratory.

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 interpret the original developing laboratory referenced in the statute to be the same laboratory that offers and furnishes the test. This interpretation is 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 are several components for us to parse, and we do so consistent with our view of the statutory intent. First, we believe 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, 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. 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 may design, market, perform, and sell the test. If more than the one laboratory engages in any of one

of those activities, the test would not meet the criteria to be an ADLT. If our proposal is finalized, we would not expect to see more than one applicable laboratory report applicable information for an ADLT.

Next, the statute permits a successor owner to the original developing laboratory to sell the test without disqualifying the test for ADLT status. We propose 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 believe the language in this regulation appropriately applies to the wide range of potential changes in ownership for laboratories. Specifically, we propose to incorporate the scenarios described in § 489.18(a) as follows. 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.* 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 above, 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 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. If this proposal is finalized, we would expect 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 are soliciting comments on our proposed definition of successor owner and, in particular, whether different change of ownership requirements may be more appropriate for the laboratory industry.

To summarize, we propose to implement the first part of the ADLT definition in section 1834A(d)(5) of the Act by stating that an ADLT is a CDLT covered under Medicare Part B that is marketed and performed only 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. We would define the terms “single laboratory” and “successor owner” in § 414.502. If this proposal is finalized, we plan to monitor compliance by confirming that applicable information for each ADLT is reported by a single laboratory. As part of that process, we would confirm that each applicable laboratory that reports applicable information for an ADLT has a single CLIA certificate.

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 interpret 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

<sup>1</sup> 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.

molecular pathology analyses. Therefore, we are proposing 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, 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” indicates 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(s), or the probability of an individual’s response to a particular therapy(ies). Furthermore, the statute requires the result to be a single patient-specific one, so 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(ies). We are also proposing 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 derive from 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 expect that 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 propose 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 reflect 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 distinct 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 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. According to the FDA’s “Overview of Medical Devices and Their Regulatory Pathways” (available on the FDA’s Web site at <http://www.fda.gov/>), a PMA refers to the scientific and regulatory review necessary to evaluate the safety and effectiveness of devices that were found either not substantially equivalent through the 510(k) [Premarket Notification] process or devices for which insufficient information exists to determine that general controls (Class I) and special controls (Class II) would provide a reasonable assurance of its safety and effectiveness. To obtain FDA approval of a device, an applicant must submit a PMA which contains valid scientific evidence to assure that the device is safe and effective for its intended use(s). We further note that FDA regulations exempt certain low-risk devices from approval or clearance and allow them to be legally marketed immediately without any form of premarket approval or clearance. Since criterion B of section 1834A(d)(5) of the Act requires FDA approval or clearance, we do not intend for this criterion to cover any devices that are, by

regulation, exempt from FDA approval or clearance. We propose 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. This process would be outlined through subregulatory processes prior to January 1, 2016.

To implement criteria A and B, we would establish guidelines for laboratories to apply for ADLT status and submit documentation to support their application. For example, 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 note in section II.F. of this proposed rule, 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 subsection” (that is, subsection (a)), it does not apply to subsection (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 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 subsection (a), per section 1834A(a)(11) of the Act. However, we note 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 cannot guarantee that 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 such 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 Section II.F of this rule 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. At this time, we are not proposing to exercise this authority; 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) 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 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 interpret 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 propose 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 would 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 full discussion of our proposed payment policies for new ADLTs is provided in section II.H.3. of this proposed 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 that is the data collection period and the timeframe for the data reporting period. In this section, we propose to define the terms "data collection period" and "data reporting period." In determining what the 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. Except for the first data collection period (which we discuss in this section), we believe 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 have chosen 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 coordinates with the timing of the CLFS payment schedule, wherein updated CLFS payment rates are in effect on January 1 of each year. We also believe 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 CMS. 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 believe that having the data collection period immediately precede the data reporting period will result in more accurate reporting by laboratories and,

thus, more accurate rate setting by CMS, because laboratories will have more recent experience, and therefore, be more familiar with the information they are reporting. Further, starting the data reporting period immediately after the data collection period will limit the lag time between reporting applicable information and the use of that applicable information to determine Medicare CLFS payments, thus ensuring that CMS is using the most recent data available to set CLFS payment rates. For these reasons, we propose 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 are proposing a special rule for the 2015 data collection period, which would begin July 1, 2015, and end December 31, 2015. While our preference would have been for the data collection period to be a full calendar year, as we are proposing for subsequent data collection periods, and for it to begin after publication of proposed and final rules implementing section 1834A of the Act, we believe the statute contemplates 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, requires 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 be in 2015. As the statute indicates that a data collection period could be a 12-month period, and data collection requirement regulations do not have to be complete until June 30, 2015, we believe the statute anticipates 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 CMS 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 believe it is reasonable to limit the time period of the first data collection period to 6 months, which is 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 believe a full calendar year of data will be the most robust and comprehensive for setting CLFS payment rates, we believe the 6-month data collection period in 2015 will still provide sufficient, reliable data with which to set rates that accurately reflect private payor rates. Therefore, we are proposing to include in the definition of data collection period in § 414.502 that the data collection period for 2015 is 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 believe 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 begin on July 1, 2015, and end on December 31, 2015, and the data reporting period would be January 1, 2016 through March 31, 2016. We believe a 3-month data reporting period is a sufficient amount of time for applicable laboratories to report applicable information to CMS. It would give CMS adequate time to calculate CLFS payment amounts, upload the CLFS rates on Medicare's claims processing systems, and make that data publicly available (tentatively, first in September and then a final version in

November) before the CLFS rates 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 believe 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 are proposing that the definition of "data reporting period" in § 414.502 is 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 data collection period, the data reporting period, and CLFS rate year for which the data will be used under our proposal for CDLTs.

TABLE 1—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 below, applicable information must be reported annually for ADLTs and will follow the above data collection schedule on an annual basis after the first data collection period, which will be for the first and second quarters of the new ADLT initial period, and reported to CMS by the end of the second quarter of the new ADLT initial period (described in more detail below).

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 discussed in section II.D.1., we are proposing 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 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 propose to establish these data reporting requirements in § 414.504(a) of the regulations.

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 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 indicate 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 realize the amount of applicable information could be voluminous for those applicable laboratories that offer a large number of tests. However, we believe 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. This requirement means that 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 would only require applicable laboratories to report the minimum information necessary to



enable us to set CLFS payment rates. We will 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 will 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 are proposing 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 believe 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 are proposing 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). This consistency is important so that after the new ADLT initial period is over, all CLFS payment rates (for CDLTs and ADLTs) will be posted publicly at the same time. Further, CMS updates all of its payment systems on the basis of a calendar quarter, and we believe consistency with all other CMS data systems will 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 that applicable laboratories would be reporting applicable information for new ADLTs during a calendar quarter. Further, if an initial period of three quarters ends during a calendar quarter, CMS 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 propose to start the initial period on the first day of the first full calendar quarter following first day on which a new ADLT is performed. We propose 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 CDLT payment methodology in section II.H.1.) for a new ADLT after the new ADLT initial period. We propose to codify the reporting requirement for new ADLTs in § 414.504(a)(3).

The following is an example of the 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 three 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, which would be the 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—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 ....<br>01/01/2018–12/31/2018 .... | By 09/30/2017 .....   | 2018–2019.<br>2020.     |

We welcome comments on these proposals and on how to make the data reporting process work as efficiently as possible.

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

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 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 note 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 are proposing 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.

## 2. Data Certification

Section 1834A(a)(7) of the Act requires that an officer of each applicable laboratory must certify the accuracy and completeness of the reported information required by section 1834A(a) of the Act. We propose 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 will specify the processes for certification in subregulatory guidance prior to January 1, 2016.

### *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, this 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 therefore we interpret these protections as applying to the applicable information that applicable laboratories report to CMS under proposed § 414.504(a). We do not read 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).

As we discuss in more detail in section II.H.1., we will use the applicable information reported under proposed § 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 believe continuing to publish this limited information would allow us to be compliant 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 CMS to administer and enforce the new Medicare payment system for CDLTs. For example, it may be necessary to disclose to the HHS Office of Inspector General 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 are proposing to add those entities to the list of entities in § 414.504(f) to which CMS 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. In the event we determine it necessary to disclose confidential information for other circumstances, we would notify the public of the reasons through a **Federal Register** announcement or via a CMS Web site publication.

Also, we believe 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. That is because, as explained in section II.C. of this proposed rule, ADLTs are offered and furnished only by a single laboratory. Thus, we believe publishing the test code and associated CLFS payment rate for an ADLT would indirectly reveal the identity of the laboratory because only the single laboratory is 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 because we need to publish the CLFS 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 will not publish information that directly discloses a laboratory's identity, but we cannot prevent the public from associating CLFS payment information for an ADLT to 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 do not expect this prohibition to be problematic as applicable laboratories will be reporting applicable information

to CMS and not the MACs. When a MAC sets rates under our new policies, we would 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, which is, it would only disclose pricing information to the extent that it needs to process and pay a claim.

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

### *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 propose 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 deleted.

“G codes” are temporary HCPCS level II codes used by CMS 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. CMS has used G codes for laboratory tests that do not have CPT codes but for which CMS makes payment, or in situations where CMS wants 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, but was not required to do so. Before we discuss each of the three provisions, we address several specific references in the statute that we believe need clarification.

In the three coding provisions, the statute requires us to “adopt,” “assign,” and “establish” codes or identifiers. We believe those terms are 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 approved or cleared 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. In section II.C.1. of this proposed rule, we proposed a definition for new ADLTs, and in section II.C.2., we discuss what it means for a laboratory test to be cleared or approved by the FDA. We are applying those interpretations here. We understand 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 would utilize 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, any G code that we adopt under this provision would be effective for up to two years, unless we believe it is 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.

#### 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 believe our existing coding process is consistent with the requirements of section 1834A(e)(2) of the Act. Accordingly, we would utilize 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 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 is used to describe more than one existing CDLT that is cleared or approved by the FDA. For instance, 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.

Section 1834A(e)(2)(B) of the Act requires CMS to publicly report the payment rate for the existing ADLT or test that is cleared or approved by the FDA by January 1, 2016. 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 section 1834A(e)(2) existing laboratory tests, we would be able to report the payment rate for them by January 1, 2016. There may be other tests in the category of section 1834A(e)(2) existing laboratory tests that are currently being priced for January 1, 2016, and that are already being paid by the MACs. (See <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/Clinical-Lab-Codes-for-CY-2016.pdf> for a list of codes discussed at the Annual Public Meeting on July 16, 2015 that we are currently in the process of pricing for January 1, 2016.) As these tests are already being paid by MACs, we would be able to publicly report their payment amounts by January 1, 2016.

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 make available on the CMS Web site prior to January 1, 2016. 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.

#### 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 utilize 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 believe the requirements of this section will be met by the existing HCPCS coding process. Therefore, we intend to implement section 1834A(e)(3) of the Act using our current HCPCS coding system. If a laboratory or manufacturer specifically requests from us a unique identifier for tracking and monitoring an ADLT or an FDA cleared or approved or cleared CDLT, we would assign it a unique HCPCS code if it does not already have one.

#### 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 propose to calculate the weighted median for CDLTs, we are providing examples of several different scenarios. These examples are meant to show how we plan to determine the weighted median and not to be exhaustive of every possible pricing scenario. As depicted in Table 3, suppose that applicable laboratories report the following private payor rate and volume information for three different CDLTs.

TABLE 3—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 3 is shown again as Table 4

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 4—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 4 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 5.

TABLE 5—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               |

TABLE 5—EXAMPLE OF THE CALCULATION OF THE WEIGHTED MEDIAN—Continued

|                                     | Test 1             |
|-------------------------------------|--------------------|
|                                     | Private payor rate |
| 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 by 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 6), 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 6—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 7), 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 7—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, irrespective of how many different private payor rates there are for a given test. In other words, 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 8 illustrates how we propose to calculate the weighted median rate for a test under this scenario:

TABLE 8—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 9).

TABLE 9—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 are proposing 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 OPSS). In CY 2014, we finalized a policy to package certain CDLTs in the OPSS (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17)). Under current policy, certain CDLTs that are listed on the CLFS are packaged in the OPSS 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 OPSS 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 OPSS and are listed on the CLFS, they are paid at the CLFS payment rates outside the OPSS 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 OPSS 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 OPSS packaging policy.<sup>2</sup> As these are payment policies that pertain to the OPSS, we will implement them in OPSS 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 propose 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 update, or other adjustment). As discussed previously in this section, 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, 2017, 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 believe section 1834A(b)(4)(B) of the Act is clear that Congress intended there be no annual update adjustment for tests paid under section 1834A of the Act. Therefore, we are proposing 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.

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

<sup>2</sup> For the CY 2016 OPSS proposed rule, we have proposed changes to the packaging policy described above. See 80 FR 39235 for more information.

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 (defined in § 414.502 and discussed in sections II.H.3. and H.6. of this proposed rule).

For 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. As a second example, 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, CMS calculates 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 believe applying the maximum applicable percentage reduction from the prior year's Medicare payment amount, rather than from the weighted median rate for CY 2016, is 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."

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. As discussed in section II.B.1. of this proposed rule, 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, we must decide 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. Under option 1, 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 believe, 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 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 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 believe, 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 are proposing option 2 (NLAs only) for purposes of applying the 10 percent reduction limit to CY 2017 payment amounts because we believe the statute intends CLFS rates to be uniform nationwide, which is why it precludes any geographic adjustment. In other words, we are proposing 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 are proposing 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 10 illustrates the phase-in reduction for the two hypothetical examples presented above:

TABLE 10—PHASE-IN REDUCTION FOR 2 EXAMPLES

|              | NLA     | Private payor rate | 10% Max. reduction | 2017 Rate | 10% Max. reduction | 2018 Rate | 10% Max. 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     |

### 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 laboratories to report applicable information 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 subsection (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 section II.D.3. of this proposed rule, we discuss our proposal to require the initial period, which we propose 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 are proposing that the payment amount for the new ADLT will equal the actual list charge, as defined below, during the new ADLT initial period. Accordingly, we propose 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 believe 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. 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 recognize there may be more than one publicly available rate, in which case we believe

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 would 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.

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” suggests 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 propose 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 would 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 are proposing 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 will outline the new ADLT application process in detail in subregulatory guidance prior to January 1, 2017.

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 need to establish a payment amount for the test during that span of time. Similar to how CMS pays 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 CMS pays at actual list charge. For example, 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 propose to reflect the payment amount for a new ADLT prior to the new ADLT initial period at § 414.522(a)(2) to specify the payment amount 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; the payment amount will 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 propose 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 will continue to apply until the year following the next data collection period, per section 1834A(d)(3) of the Act. The following is an example 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 CMS by the last day of Q3 of CY 2017. CMS 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 CMS 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.

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

Section 1834A(d)(4) of the Act requires that after the new ADLT initial period, if the Medicare payment amount during the new ADLT initial period (that is, the actual list charge) is more than 130 percent of the Medicare payment amount determined using the weighted median of private payor rates that is applicable after the new ADLT initial period, the Secretary shall recoup the difference between the Medicare payment amounts during the initial period and the Medicare payment amount based on the weighted median of private payor rates. We believe the statute is directing the Secretary to 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. For 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 is 150 percent of the Medicare payment amount based on the weighted median rate. We believe the statute is directing 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 amounts” which means the Medicare payment amount based on actual list charge and the Medicare payment amount based on the weighted median rate. The statute directs 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 are proposing at § 414.522(c) to specify that if the difference between the Medicare payment amounts for an ADLT during the new ADLT initial period based on actual list charge and the weighted median rate exceeds 130 percent, CMS will recoup the entire amount of the difference between the Medicare payment amounts. We further note that if the 130 percent statutory threshold is not exceeded, we are proposing to not recoup at all. Thus, for instance, if the weighted median rate is \$100 and the Medicare payment amount during the initial period is \$130 or lower, the statutory threshold of 130 percent is not exceeded and we will not pursue any recoupment of payment.

To determine whether the recoupment provision applies, we propose to compare the Medicare payment amount based on actual list charge paid during the new ADLT initial period and the weighted median rate (as calculated from the first time reporting of new ADLT applicable information) for each ADLT. If the difference between these two amounts exceeds 130 percent, the laboratory will be required to refund the difference in total Medicare payments based on actual list charge and the weighted median rates. In other words, if the actual list charge for a new ADLT is 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, CMS 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). CMS also intends to issue further guidance on the operational procedures for recoupment of the new ADLTs that exceed the 130 percent threshold.

#### 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, 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 are proposing to use crosswalking and gapfilling to establish the payment amounts for existing ADLTs. We would 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).

#### 6. Payment for New CDLTs That Are Not ADLTs

Section 1834A(c) of the Act establishes 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 set forth 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 69701–69704) published on December 1, 2006.

We interpret 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 will need 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 this 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 propose to add a reference to 42 CFR part 414, subpart A, entitled “General Provisions,” in § 414.1. In addition, we propose 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 propose 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 propose to delete “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 noted previously, 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 are proposing 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 would specify 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 specifically 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 are not proposing 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.”

#### b. Crosswalking and Gapfilling

*Background:* As we explained in the CY 2008 PFS final rule with comment period (71 FR 66275–76), 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 assign 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 are proposing 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 payers; 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, CMS accepts reconsideration requests in written format for 60 days after making a determination of the basis for payment (either crosswalking or gapfilling) regarding whether CMS 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 CMS decides to change the amount of payment for the code, the new payment amount would be effective January 1 of the year following the reconsideration.

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 enactment date of PAMA. We note that the annual crosswalking and gapfilling process has already occurred for codes on the 2015 CLFS, and is currently underway for codes on the 2016 CLFS. We are proposing 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 have been 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 will remain in effect until January 1, 2017. We would update § 414.508 by changing the introductory language to limit paragraphs (a) and (b) (which would be redesignated as paragraphs (a)(1) and (a)(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 (b)(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 are proposing to use comparable crosswalking and gapfilling processes that are modified to reflect the new market-based payment system under section 1834A of the Act. As discussed previously, beginning January 1, 2017, the payment methodology established under section 1834A(b) of the Act will replace the current payment methodology under sections 1833(a), (b), and (h) of the Act, including NLAs and local fee schedule amounts. Thus, we are proposing 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 are not proposing 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 are proposing to establish the following crosswalking process in § 414.508(b)(1), which does not rely on NLAs or local fee schedule amounts:

*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.

- CMS assigns 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, we are not proposing 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. At this time, we are not proposing any additional factors to determine gapfill amounts. If we decide to establish additional gapfilling criteria, we will do so through notice and comment rulemaking.

We are proposing 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 are proposing 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). Section 414.508(b)(2) would state that gapfilling is used when no comparable existing CDLT is available. We would state in § 414.508(b)(2)(i) that, 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:

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

We note 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 previously, 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 are proposing 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 believe the initial period is 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 would 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, CMS accepts 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. After considering the comments received, CMS may 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). However, as previously noted in this section, the NLA will no longer be applicable on and 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 propose 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 would also 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.

### c. Public Consultation Procedures

*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 section II.J.1, we describe the Advisory Panel on CDLTs (the Panel). We are proposing 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 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.

*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, CMS develops and makes available to the public (through

an Internet Web site and other appropriate mechanisms) a list of:

- 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, and a request for public written comments within a specified time period on the proposed determination; 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 CMS 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 are proposing to amend § 414.506 to explicitly indicate that, for a new CDLT on or after January 1, 2017, we will provide an explanation of gapfilled payment amounts and how we took into account the Panel’s recommendations. Specifically, we are proposing to add paragraphs (3) and (4) to § 414.506(d). In § 414.506(d)(3), we would specify that, for a new CDLT, in applying paragraphs (1) and (2), CMS will provide an explanation of how it took into account the recommendations of the Advisory Panel on CDLTs. In § 414.506(d)(4), we would specify that, for a new CDLT, in applying paragraphs (1) and (2) 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.

Under these provisions, we would 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/.*

### 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 by 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 CMS 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 CMS 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 receive more than 50 percent of their Medicare revenues from the CLFS and the PFS. Or, they may be laboratories that received less than \$50,000 a year in Medicare revenues under the CLFS (or less than \$25,000 in Medicare revenues under the CLFS for the proposed 6-month data collection period for CY 2015). As we stated in section II.A. of this proposed rule, we estimate that in 2013 there were 17 laboratory tests with utilization completely attributed to entities that would not have been applicable laboratories because they did not meet the \$50,000 threshold.

- *Special Situations Involving ADLTs.* It is also possible that a laboratory that performs a test that would qualify to be an ADLT, does not meet the definition of an applicable laboratory and, therefore, cannot report applicable information. As discussed in section II.C. of this proposed rule, 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, this situation could occur if the only laboratory performing the test did not receive more than 50 percent of its Medicare revenues from the CLFS and the PFS, or received less than \$50,000 a year in Medicare revenues under the CLFS (or less than

\$25,000 in Medicare revenues under the CLFS for the proposed 6-month data collection period for CY 2015).

- *Other Reasons Not Specified.* It is possible we may not receive applicable information for a laboratory test if an applicable laboratory fails to comply with the reporting requirements under section 1834A of the Act for which the laboratory may be penalized under section 1834A(a)(9) of the Act (we address CMPs for non-reporting in section II.E.1. of this proposed rule). There may also be other reasons we cannot anticipate where we might not receive applicable information for a laboratory test in a data collection period.

In the event we do not receive applicable information for a laboratory test that is provided to a Medicare beneficiary, 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 propose to use crosswalking and gapfilling using the proposed definitions in § 414.508(b)(1) and (2) to establish a payment rate on or after January 1, 2017, which would remain in effect until the year following the next data reporting period. 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 CMS receives no applicable information in a subsequent data reporting period, we would use crosswalking or gapfilling methodologies to establish the payment amount for the test. In other words, if in a subsequent data reporting period, no applicable information is reported, CMS would 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 are not proposing this approach because we believe carrying over previous payment rates

would not reflect changes in costs or pricing for the test over time. We understand the purpose of section 1834A of the Act is to 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 believe 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 serves an analogous purpose by periodically reconsidering the payment rate of a test using gapfilling or crosswalking. We expect to continue to evaluate our proposed approach to setting rates for laboratory tests paid on the CLFS with no reported applicable information as we gain more programmatic experience under the new CLFS. 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 propose that for a CDLT, including ADLTs, for which we receive no applicable information in a data reporting period, CMS will determine the payment amount based on either crosswalking or gapfilling. We propose to add paragraph (g) to § 414.507 to specify that for CDLTs for which CMS receive no applicable information, payment is made based on the crosswalking or gapfilling methods described in § 414.508(b)(1) and (2).

#### *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, however, 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, a public comment period, and issuance of a final LCD followed by at least a 45-day notice period prior to the policy becoming effective. In addition, there are opportunities for public meetings. 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 CMS has issued at 42 CFR part 426. The LCD appeals process establishes a process for 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) 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 CMS 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 needs to conduct the necessary 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 and the volume of these test requires the agency to seriously consider consolidating all MAC CDLT processes into 1–4 MACs. Therefore, we are seeking input from stakeholders on the components and feasibility of moving forward with consolidation all MAC CDLT process into 1–4 MACs.

For instance, should only coverage policies be developed by a smaller number of MACs, issues could arise for the other A/B 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, CMS would need to consider that the MAC processing the laboratory claim will (in most cases) not be the same MAC that processes the claim of the ordering physician. This may complicate the development of a full profile of the ordering physicians' practice patterns for quality and medical necessity assessment purposes. Accordingly, at this time, we are requesting public comment on the benefits and disadvantages of implementing the new discretionary authority to consolidate the number of MACs developing LCDs for CDLTs. We are also soliciting comments on whether CMS should utilize the broadest discretion provided by the statute to task four or fewer MACs with the responsibility of both writing CDLT-related LCDs and processing all CDLT claims. We also

invite comments on other alternatives permissible within the scope of the new legislative authority that CMS should consider which are not outlined here.

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 ability of the agency to develop 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 CMS would reduce both the number of MACs writing coverage policies for CDLT services and the number of MACs processing CDLT claims, could take upwards of 5 to 6 years. To establish centralized LCDs for all CDLTs would probably involve an initial build-up and then a steady-state investment of between \$10 and \$15M per year. To create regional lab claims processors (in addition to development of LCDs) would involve higher set-up costs, and some steady-state costs. The reduction in A/B MACs operating costs would likely not fully offset the cost of the specialty lab MACs since the A/B MACs would continue to develop LCDs for other Medicare benefits. CMS is not aware of PAMA funds for this activity, and so CMS would need to obtain any needed incremental implementation and operational funding through the regular Program Management appropriation process. However, prior to the agency committing to any direction regarding the number of MACs involved and the purview of their responsibilities, we are seeking public comment on the benefits and risks of implementing the various scenarios authorized by this section of the statute.

#### 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). As discussed in section II.H.6. of this proposed rule, we are proposing 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), CMS announced the Advisory Panel on CDLTs. On April 16, 2015, CMS 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), CMS 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>.

## 2. Exemption From Administrative and Judicial Review

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

## 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. This provision was implemented via Medicare Change Request (CR) transmittal effective December 1, 2014 (Transmittal #R3056CP; CR #8837). We propose to reflect this policy in § 414.507(f).

## 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 notice of proposed rulemaking need not be reviewed by the Office of Management and Budget.

## IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## V. Regulatory Impact Analysis

### A. Statement of Need

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

### B. Overall Impact

We have examined the impacts of this 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 proposed 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 rulemaking 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 proposed implementation of new section 1834A of the Act. As described earlier in this proposed rule, a part of this proposed rule describes a schedule and process for collecting

private payor rate information from certain laboratories. Until such time that these data are available, we are limited in our ability to estimate effects of our proposed 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 \$15 million or less in any 1 year: \$15 million for testing 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), 93 percent of medical laboratories would be considered small businesses. This rule will have a significant impact on a substantial number of small businesses or other small entities even with an exception for low expenditure laboratories.

As discussed previously in this proposed rule, we are proposing 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. Given that well over 90 percent of the Medicare enrolled laboratories paid under the CLFS are physician office laboratories, we estimate the majority of Medicare enrolled laboratories would meet the SBA definition of a small business.

As discussed in section II.D. of this proposed rule, applicable laboratories will be required to report applicable information to CMS, which 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 are specifically proposing 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) applicable laboratories to report individual claims 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 proposals will substantially reduce the reporting burden for applicable laboratories in general and small businesses in particular. We discuss reporting requirements further in section V.E. of this proposed rule.

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 2017. 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 proposed 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 would provide a reasonable representation of the impact of the proposed changes to the CLFS on small businesses (see Table 11). As

illustrated in Table 11, the effect on the Medicare program is expected to be \$360 million less in Part B program payments for CLFS tests furnished in FY 2017. The 5-year impact is estimated to be \$2.94 billion less and the 10-year impact is expected to result in \$5.14 billion less in program payments. As discussed in section I.B., overall, Medicare pays approximately \$8 billion a year under the current CLFS for CDLTs. Using our estimated amount of proposed changes in CLFS spending, we estimate an overall percentage reduction in revenue of approximately -4.5 percent for FY 2017 (-\$360 million/\$8 billion = -4.5 percent); a 5-year percentage reduction of about 7.4 percent (-\$2.94 billion/\$40 billion = -7.35 percent) and a 10-year percentage reduction of approximately 6.4 percent (-\$5.14 billion/\$80 billion = -6.43 percent). As such, we estimate that the proposed revisions to the CLFS as authorized by PAMA would have a significant impact on small businesses.

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 603 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 proposed rule will not have a significant impact on small rural hospitals because the majority of entities paid under the CLFS and affected by this proposal 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 proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals. We request 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.

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 2015, that is

approximately \$144 million. This proposed 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 proposed rule (and subsequent 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 proposed 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 labs that billed under the CLFS). However, we note that this proposed 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

The effect on the Medicare program is expected to be \$360 million less in program payments for CLFS tests furnished in FY 2017. 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. 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 7 years of multi-factor productivity adjustments, as required by 1833(h)(2)(A) of the Act, to establish a new baseline difference between private payor rates and Medicare CLFS payment



rates of approximately 6.4 percent in 2017. The new baseline difference between Medicare CLFS payment rates and private payor rates (6.4 percent) results in an approximate savings to the Medicare program of \$360 million in FY 2017. We projected the FY 2017 Medicare savings of \$360 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 2026) after adjusting for additional productivity adjustments to determine a 10 year cost savings estimate (as illustrated in Table 11). 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.

#### E. Alternatives Considered

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

In developing this proposed rule, we considered numerous alternatives to the presented proposals. 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.

*Definition of applicable laboratory—TIN vs. NPI.* We considered defining an applicable laboratory by NPI instead of TIN. As discussed in section II.A. of this proposed rule, we believe that defining an applicable laboratory for reporting applicable information to CMS by TIN,

rather than by NPI, will result in the same applicable information being reported at a higher level and will require less reporting and will, therefore, be less burdensome to applicable laboratories. Therefore, we are proposing to define applicable laboratory by TIN rather than by NPI.

*Authority to develop a low volume or low expenditure threshold to reduce reporting burden for small businesses.* We are proposing to exercise our authority to develop a low expenditure threshold to exclude small businesses from having to report applicable information. As discussed in section II.A. of this proposed rule, we are proposing 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 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 CMS. However, by proposing a low expenditure threshold we were able to substantially reduce the number of entities required to report applicable information to CMS (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 it could potentially exclude laboratories that perform a low volume of very expensive tests from reporting applicable information. We believe that the proposed low expenditure threshold will significantly reduce the reporting burden for small businesses.

*Applicable information—Private payor rates inclusive of patient cost-sharing amounts (coinsurance, deductible) vs. private payor rates exclusive of patient cost-sharing amounts.* As we discussed in section II.B. of this proposed rule, because Medicare generally does not require the beneficiary to pay a deductible or coinsurance on CLFS services, we believe it is important for private payor rates to be reported analogous to how they will be used by Medicare to determine the Medicare payment

amount (that is, without any beneficiary cost-sharing). For this reason, we are proposing that applicable laboratories report private payor rates inclusive of all patient cost sharing. We did not propose defining applicable information as private payor payment amounts after the application of beneficiary cost sharing, because reporting rates absent of deductible and coinsurance amounts would be inconsistent with how rates are determined under the CLFS.

#### *Definition of New ADLT Initial Period.*

As explained in sections II.C.1. and II.D.3 of this proposed 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 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 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 proposed rule, if we were to start the 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 an 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).

*CMPs.* With regard to CMPs, we are proposing to adopt a similar regulation for implementing section 1834A(a)(9)(A) of the Act that applies to drug manufacturers reporting Part B drug prices under section 1847A(d)(4) of the Act. We did not include in this proposed rule a specific proposal for

effecting CMPs under the proposed CLFS. Given that CMP collections have been limited for drug manufacturers (only one case), we do not have data to provide an estimate of CMP collections under the revised CLFS established under PAMA. Nevertheless, if compliance with the section 1834A of the Act and this proposed rule is as high as occurred with reporting Part B drug prices, we expect CMP collections to be a rare event.

*Medicare payment for tests where no applicable information is reported.* As discussed in section II.H.7. of this proposed rule, in the event we do not receive applicable information for a laboratory test that is provided to a Medicare beneficiary, we propose to use crosswalking and gapfilling using the proposed definitions in § 414.508(b)(1) and (2) to establish a payment rate on or after January 1, 2017, which would remain in effect until the year following the next data reporting period. 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 CMS receives no applicable information in a subsequent data reporting period, we would use crosswalking or gapfilling methodologies to establish the payment amount for the test. In other words, if in a subsequent data reporting period, no applicable information is reported, CMS would 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 are not proposing 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 in section II.H.7., we believe reconsidering payment 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.

*Cost of data reporting activities.* As discussed in section II.D. of this proposed rule, applicable laboratories will be required to report applicable

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 do not have information upon which to develop a cost estimate for reporting applicable information, we cannot provide more information at this time. The CLFS has grown from approximately 400 tests to over 1,300 tests. While we are not able to ascertain how many private payors and private payor rates there are for each applicable laboratory, we are providing a hypothetical example to illustrate the number of records (with one record being the specific HCPCS code, the associated private payor rate, and volume) that an applicable laboratory would be required to report under this 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, it 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). Of course, this example is hypothetical and illustrative only but demonstrates the potential volume of information a given laboratory may be required to report. 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 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 of the proposed rule, we are interested in public comments from applicable laboratories on the following questions:

- How many tests on the CLFS does the applicable laboratory perform?
- For each test, how many different private payor rates does the applicable laboratory have in a given period (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 believe that these items would be important factors to consider before projecting data reporting and or record keeping requirements. We welcome comments on these questions from the public.

*Phased-in Payment Reduction.* As discussed in section II.H.2. of this proposed rule, we are proposing 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 in section II.H.2., we believe the statute intends CLFS rates to be uniform nationwide, which is why it precludes any geographic adjustment. In other words, we are proposing 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. The alternative would be 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 less 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.

**F. Accounting Statement and Table**

As required by OMB Circular A-4 (available on the Office of Management and Budget Web site at: [http://](http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf))

[www.whitehouse.gov/sites/default/files/omb/assets/regulatory\\_matters\\_pdf/a-4.pdf](http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf)), we have prepared an accounting statement in Table 11 to illustrate the impact of this proposed rule. The

following table illustrates the estimated amount of change in CLFS spending under the proposed policies set forth in this proposed rule.

**TABLE 11—ACCOUNTING STATEMENT: ESTIMATED CLINICAL LABORATORY FEE SCHEDULE TRANSFERS FROM CY 2015 TO CY 2019 ASSOCIATED WITH THE PROPOSED CHANGES TO THE CLINICAL LABORATORY FEE SCHEDULE AS DESCRIBED IN SECTION 1834A OF THE ACT**

| Category   | Estimates  |       | Year dollar |                         |                |
|--|--|-------|-------------|-------------------------|----------------|
|  |  |       | Year dollar | Discount rate (percent) | Period covered |
| Transfers  |  |       |             |                         |                |
| Federal Annualized Monetized Transfers (in millions) ..... | - 489  | - 480 | 2015        | 3                       | 2016–2025      |
|  |  |       | 2015        | 7                       | 2016–2025      |
| From Whom to Whom .....                                    | Federal Government to Entities that Receive Payments under the Medicare Clinical Laboratory Fee Schedule |       |             |                         |                |

  

| Estimate (in millions)   | 2015 | 2016 | 2017  | 2018  | 2019  | 2020  | 2021  | 2022  | 2023  | 2024  | 2025  | 2026  | 5-year impact 2016–2020 | 10-year impact 2016–2025 |
|--------------------------|------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------------------------|--------------------------|
| FY Cash Impact (with MC) |      |      |       |       |       |       |       |       |       |       |       |       |                         |                          |
| Part B:                  |      |      |       |       |       |       |       |       |       |       |       |       |                         |                          |
| Benefits .....           |      |      | (480) | (850) | (920) | (850) | (810) | (870) | (680) | (540) | (580) | (250) | (3,910)                 | (6,830)                  |
| Premium Offset .....     |      |      | 120   | 210   | 230   | 210   | 200   | 220   | 170   | 130   | 140   | 60    | 970                     | 1,690                    |
| Total Part B .....       |      |      | (360) | (640) | (690) | (640) | (610) | (650) | (510) | (410) | (440) | (190) | (2,940)                 | (5,140)                  |

**G. Cost to the Federal Government**

If these requirements are finalized, CMS will create a data collection system, develop HCPCS codes for laboratory tests when needed, convene a FACA advisory committee to make recommendations on how to pay for new CDLTs including reviewing and making recommendations on applications for ADLTs, and undertake other implementation activities. To implement these new standards, we anticipate initial federal start-up costs to be approximately \$4 million. 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 that we are proposing in this proposed rule would 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 proposed 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 proposed rule includes proposed changes which may affect different laboratory test suppliers differently, based on the types of tests that they provide.

The previous analysis, together with the remainder of this preamble, provides an initial 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**

**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 proposes to amend 42 CFR part 414 as follows:

**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)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395r(b)(1)).

**§ 414.1 [Amended]**

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

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

**Subpart G—Payment for Clinical Diagnostic Laboratory Tests**

■ 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,” “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 CDLT covered under Medicare Part B that is marketed and performed only 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, and meets one of the following criteria:

- (1) The test—
  - (i) Must be a molecular pathology analysis of multiple biomarkers of deoxyribonucleic acid (DNA), or ribonucleic acid (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.
- (2) The test is cleared or approved by the Food and Drug Administration.

*Applicable information* means, with respect to each CDLT for a data collection period—

- (1) Each private payor rate.
- (2) The associated volume of tests performed corresponding to each private payor rate.
- (3) The specific HCPCS code associated with the test.
- (4) Does not include information about a test for which payment is made on a capitated basis.

*Applicable laboratory* means 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, as these terms are defined in this section;

- (2) Is itself a laboratory, as defined in § 493.2 of this chapter, or, if it is not itself a laboratory, has at least one component that is a laboratory, as defined in § 493.2 of this chapter, for which the entity reports tax-related information to the IRS using its TIN; and

- (3) In a data collection period, receives, collectively with its associated NPI entities, more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Part 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) Subpart G of this part;
- (ii) Subpart B of this part; and
- (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 subpart G of this part; and
- (5) For all subsequent data collection periods receives, collectively with its associated NPI entities, at least \$50,000 of its Medicare revenues from subpart G of this part.

*Data collection period* is the calendar year during which an applicable laboratory collects applicable information and that immediately precedes the data reporting period, except that for 2015, the data collection period is July 1, 2015 through December 31, 2015.

*Data reporting period* is the 3-month period during which an applicable laboratory reports applicable information to CMS and that immediately follows the 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, 2017.

*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 first day on which a new ADLT is performed.

*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 amount that was paid by a private payor for a CDLT after all price concessions were applied.
- (2) Includes any patient cost sharing amounts if applicable.

*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.

*Single laboratory*, for purposes of an ADLT, means a facility with a single CLIA certificate as described in § 493.43(a) and (b) of this chapter.

*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 laboratory that designed the test through any of the following circumstances:

- (1) *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.
- (2) *Unincorporated sole proprietorship*. Transfer of title and property to another party constitutes change of ownership.
- (3) *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.

Transfer of corporate stock or the merger of another corporation into the original

developing laboratory corporation does not constitute change of ownership.

(4) *Leasing.* The lease of all or part of the original developing laboratory constitutes change of ownership of the leased portion.

\* \* \* \* \*

*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) *General Rule:* In a data reporting period, an applicable laboratory must report applicable information for each CDLT furnished during the corresponding data collection period, as follows—

(1) For CDLTs that are not new CDLTs, every 3 years beginning January 1, 2016.

(2) For ADLTs that are not new ADLTs, every year beginning January 1, 2016.

(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 and the date the new ADLT is first performed.

(d) To certify data integrity, 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, 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 an applicable laboratory has failed to report, or made a misrepresentation or omission in reporting, applicable information, the Secretary may apply a civil monetary penalty in an amount of up to \$10,000 per day 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) An entity that does not meet the definition of an applicable laboratory may not report applicable information.

■ 7. Section 414.506 is amended by revising the introductory text and paragraph (d)(1), and adding paragraphs (d)(3), (d)(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), and a request for written public comments within a specified time period on the proposed determination; and

\* \* \* \* \*

(3) On or after January 1, 2017, 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, 2017, 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, 2017, 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 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—

(1) 2017—10 percent of the national limitation amount for the test in 2016.

(2) 2018—10 percent of the payment rate established in 2017.

(3) 2019—10 percent of the payment rate established in 2018.

(4) 2020—15 percent of the payment rate established in 2019.

(5) 2021—15 percent of the payment rate established in 2020.

(6) 2022—15 percent of the payment rate established in 2021.

(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 December 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, 2016, payment is made 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, 2016, 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, 2017, 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 § 414.509(a)(3) 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 difference between the actual list charge of a new ADLT and the weighted median established under the payment methodology described in § 414.507 exceeds 130 percent, CMS will recoup the entire amount of the difference between the ADLT actual list charge and 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: September 4, 2015.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Dated: September 23, 2015.

**Sylvia M. Burwell,**

*Secretary, Department of Health and Human Services.*

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