June 23, 2014

VIA E-MAIL AND FIRST CLASS MAIL

Ms. Anne E. Tayloe Hauswald, Director
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Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Ms. Hauswald,

Thank you for meeting with us on May 19, 2014 to discuss implementation of Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), which adds Section 1834A to the Social Security Act to reform reimbursement rate setting under Medicare's Clinical Laboratory Fee Schedule ("CLFS").[1] We found it to be a productive meeting, and we appreciated the opportunity to share with you our preliminary thoughts on implementation of the law and to hear from you about the agency's current thinking.

This memo provides background and recommendations on the legal, policy, and implementation issues raised by specific provisions included in Section 216 of PAMA, which modifies the reimbursement rate methodology under the CLFS for the first time in three decades. We have organized our discussion around five general categories of issues, questions, and suggestions related to the CLFS reform provisions contained in Section 216: (1) reporting of private payor rates and volumes; (2) Medicare payment rate development; (3) coding; (4) coverage; and (5) steps involved in the overall implementation of the new law.

As we review the complex new reporting requirements of the law, we see an urgent need for CMS to provide clear and consistent direction to the laboratories affected by these requirements as soon as possible to ensure that implementation proceeds smoothly. There are many technical factors that will impact laboratory compliance, and we urge CMS to solicit laboratory input on these matters. We believe that the creation of a new expert advisory panel could provide CMS with assistance as it moves forward in this area.

I. REPORTING

Reporting of payment rates and volumes for clinical diagnostic laboratory tests and advanced diagnostic laboratory tests ("ADLTs") is perhaps the most critical area for discussion

[1] Pub. L. 113-93 (codified at 42 U.S.C. § 1395m-1 (2014)).

and consideration. Reporting could begin as early as January 1, 2016, and the statute requires regulations to be issued not later than June 30, 2015. There are a remarkable number of details to be worked out before laboratories can begin to prepare to report data to CMS. The way in which CMS defines the parameters, participants, methods, and time frames for reporting can have a substantial impact on the rates that the Medicare program pays for clinical laboratory tests. It will be an enormous undertaking for CMS to prepare to receive millions of pieces of information from thousands of laboratories and for each one of those laboratories to collect, organize, and transmit the data. While we recognize that CMS must address many facets of implementation concurrently, reporting is one area that we believe should be a primary focus for the agency in the near term.

A. The Law

Beginning January 1, 2016 and generally every three years thereafter, an applicable laboratory is to report certain information to the Secretary about private payor data for laboratory tests. An "applicable laboratory" is a laboratory that receives a majority of its Medicare revenue under the CLFS, the Physician Fee Schedule ("PFS"), or the new Section 1834A of the Social Security Act, as added by PAMA. For most clinical diagnostic laboratory tests furnished during a specified data collection period, an applicable laboratory must report both the payment rates paid by each private payor for the tests during the period and the volume of such tests for each private payor for the period (except for tests paid on a capitated basis). When 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 lab is to report each of those rates and the corresponding volumes (the Secretary may allow aggregate reporting of this data starting January 1, 2019). A "private payor" is "a health insurance issuer and a group health plan," a Medicare Advantage plan, or a Medicaid managed care organization.

The timetable for reporting is different for ADLTs.[2] During the initial reporting period, an applicable laboratory is to report private payor rates and volumes for ADLTs no later than the "last day of the second quarter" of such initial period, and afterward, reporting is to be annual for these tests (rather than every three years).

Information reported by an applicable laboratory is confidential and is not to be disclosed by CMS or any Medicare contractor in a form that reveals the identity of a payor or laboratory, except "as the Secretary determines to be necessary to carry out this section," or to the Comptroller General of the United States, the Congressional Budget Office, or MedPAC.[3]

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[2] An ADLT is a laboratory test covered under Medicare that is offered and sold only by the developing lab (or its successor) and that meets one of the following criteria: (a) the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; (b) the test is approved or cleared by the Federal Food and Drug Administration ("FDA"); or (c) the test meets other similar criteria established by the Secretary. Social Security Act § 1834A(d)(5) (42 U.S.C. § 1395m-1(d)(5)).

[3] Social Security Act § 1834A(a)(10) (42 U.S.C. § 1395m-1(a)(10)).

B. Issues, Questions, and Suggestions

1. "Applicable laboratories". The law defines an "applicable laboratory" as a "laboratory" that receives the majority of its Medicare revenues under the CLFS, the PFS, or the new section 1834A of the Social Security Act, yet neither the term "laboratory" nor the term "revenues" is defined in PAMA or elsewhere in the Social Security Act. The law also permits CMS to exclude certain laboratories from the definition of "applicable laboratory" by establishing low volume or low expenditure thresholds. Laboratory services can be furnished by a variety of entities, and CMS will have to determine what types of laboratories are encompassed by the term "applicable laboratories." The range of laboratories includes:

- Independent clinical laboratories: national, regional, and local laboratories that are not affiliated with hospitals or physician offices. Some independent clinical laboratories perform a full range of laboratory testing, while others offer a handful of specialized tests. Specimens may be collected in the community by the laboratory or collected and referred by physicians, health care facilities, and other laboratories and sent to independent laboratories.

- Hospital laboratories: perform laboratory testing for the benefit of hospital inpatients and outpatients. Many hospitals also have laboratory outreach programs through which they serve members of the community, much in the same way that many independent clinical laboratories do.

- Physician office laboratories: Many physician offices have in-office laboratories and perform point-of-care testing for their own patients. They also may perform moderate- and high-complexity laboratory tests and tests for other physicians, as well.

For hospitals, CMS first must determine whether an "applicable laboratory" includes a hospital laboratory, where a majority of the laboratory's Medicare revenue comes from the CLFS, the PFS, or the new Section 1834A of the Social Security Act. It would not be appropriate to look at the sources of the entire hospital's Medicare revenue. If Congress intended for CMS to look at an entire hospital's revenues, then it presumably would have used a broader term in the law, such as "entity," rather than using the narrower term "laboratory."[4] The law is clear that the appropriate inquiry is from what sources a ***laboratory's*** Medicare revenues are derived. To answer that, it is appropriate to look at the laboratory within the hospital, which is a distinct and identifiable cost center.

The second question is what is meant by "revenues." A hospital may provide laboratory services in three different ways, but in most situations, it will not receive what would be considered laboratory "revenues." First, it can provide laboratory services to hospital inpatients, in which case the hospital is paid a bundled rate (a global DRG payment) that includes the

[4] *See* Social Security Act § 1834A(a)(2) (42 U.S.C. § 1395m-1(a)(2)) ("the term 'applicable laboratory' means a laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section, section 1833(h), or section 1848.").

laboratory services. The laboratory receives no separate "revenues" attributable to the laboratory services in this case. Second, a hospital laboratory can provide services to hospital outpatients. As results of the new bundling requirement that CMS established in the CY 2014 Hospital Outpatient Prospective Payment System ("OPPS") rule, hospitals are not paid separately for most laboratory services furnished to outpatients.[5] The payment for the laboratory service is included in the Ambulatory Payment Classification ("APC") payment; therefore, the hospital laboratory does not receive any separate laboratory "revenues" in this situation either. Finally, a hospital can provide "outreach" services, *i.e.*, where a hospital obtains specimens from physicians who see patients in their own offices, just like independent clinical laboratories do. In that case, a hospital is paid separate laboratory "revenue" for those services under the CLFS.[6]

In sum, a hospital laboratory has separately-identifiable "revenues" when it is paid separately for its outreach testing services furnished to non-patients.[7] CMS has noted on several occasions that when a hospital furnishes testing services for non-hospital patients, it is "functioning as an independent clinical laboratory."[8] Thus, it seems reasonable, and justified by the terms of the statute, to determine that a hospital laboratory performing outreach testing is an "applicable laboratory."

Moreover, it is reasonable as a matter of policy to require hospitals to be included in rate reporting for purposes of Section 216 of PAMA. In drafting this law, Congress clearly contemplated that the Medicare rates that CMS derives from private payor data would apply to laboratory tests furnished by hospital laboratories when such tests are not part of a bundled payment (*i.e.*, when provided on an outreach basis).[9] Therefore, it stands to reason that the same hospital laboratories should report their private payor data to CMS for those tests that are not bundled. Because Congress's intent is for Medicare rates to approximate private market rates for clinical laboratory tests, data reflecting the entire market must be included to set rates accurately.[10]

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[5] *See* 78 Fed. Reg. 74229, 74939 (Dec. 12, 2013).

[6] CMS itself has recognized these distinctions, and it recently has given instructions to hospitals on how to distinguish separately-billable outreach services from outpatient services that are bundled under an APC. *See* CMS Transmittal 2845, Change Req. 8572 (Dec. 27, 2013); *see also* CMS Transmittal 2971, Change Req. 8776 (May 23, 2014).

[7] As noted, hospitals also are permitted to be paid separately for laboratory services furnished to outpatients if those services are for molecular pathology services. However, if those payments are included as revenues, it would not affect the outcome, as they still would constitute revenues from 1833(h) of the Social Security Act, which is one of the applicable sections included in Section 216 of PAMA.

[8] *See, e.g.*, Medicare Claims Processing Manual, Chapter 16, § 10 ("When a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory…").

[9] *See* Social Security Act § 1834A(b)(1)(B) (42 U.S.C. § 1395m-1(b)(1)(B)).

[10] Congress's intent was made explicit in a colloquy between Sen. Richard Burr (R-NC), a member of the Senate Finance Committee, and Sen. Orrin Hatch (R-UT), Ranking Member of that committee. *See* 160 Cong. Rec. S2860 (daily ed. May 8, 2014). Sen. Burr noted that it was his understanding that "the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that all sectors of the laboratory market should be represented in the reporting system, including independent laboratories and hospital outreach

- ***Recommendation: Hospital laboratories performing outreach testing should be included in the definition of "applicable laboratory" and should report their private payor data for clinical laboratory tests that are not part of a bundled payment.***

Similarly, it seems appropriate that certain physician office laboratories for which the majority of Medicare revenues come from the CLFS, the PFS, or Section 1834A also should be included in the definition of "applicable laboratory" and report their private payor data. Certain physician office laboratories perform a significant number of point-of-care tests, so data from physician office laboratories may be particularly important for setting accurate rates for such tests, and physician office laboratories may perform more complex tests, as well. As noted above, if the intent is for Medicare rates to reflect market rates, then the full range of pricing data should be included. At the same time, we acknowledge that CMS must balance the importance of complete information about private payor data against the burden on physician office laboratories that may have limited resources to submit complete and accurate rate information.

- ***Recommendation: CMS should solicit public comments on the inclusion of physician office laboratories in the definition of "applicable laboratory," and it also should seek input on how to strike the appropriate balance between complete private payor market data and the burden that a reporting obligation would impose on physician office laboratories.***

2. Private payor rates and volumes. As we have discussed issues related to implementation of the law over the past several weeks, we have been reminded of the vast number of individual private payor rates paid to just a single major laboratory and the significant task of collecting and reporting each individual rate and associated volume. One laboratory may have contracts with more than a thousand private payors, as that term is defined in the law, with separate payment rates for many or all of the individual plan offerings by each of the payors, and separate payment rates for each one of the more than one thousand codes on the CLFS. The individual plans may pay different payment rates for each of the codes, depending on a number of factors. Rates also may differ for services offered in different states. These thousands of individual rates then will be multiplied by the number of applicable laboratories participating in the Medicare program and reporting their own rates. CMS's information technology challenge in accepting and organizing this much data and using it properly to calculate accurate payment rates is equaled by the information technology challenges that will be faced by each laboratory that must collect, organize, de-duplicate, and transmit data to CMS.

Recent events in California demonstrate how difficult and complex this exercise is bound to be. In 2012, the California legislature enacted similar reporting requirements to establish new payment levels for clinical laboratory tests paid for by the California Medicaid program ("Medi-

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laboratories that receive payment on a fee-for-service basis under the fee schedule." Sen. Hatch agreed, stating that "commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."

Cal"). The law requires laboratories to report their pricing information for more than 400 separate tests to the California Department of Health Care Services ("DHCS"). Affected laboratories are required to submit rates for at least their top five payors for California, not including Medicare and Medi-Cal. Many laboratories that participate in Medi-Cal had difficulty assembling the required information by the first deadline on May 31, 2013, and DHCS was forced to extend the deadline for data submission by three months in order for laboratories to complete the process. The amount of information that each applicable laboratory must report under Section 216 of PAMA dwarfs the amount that had to be reported in California. CMS should be prepared to receive an overwhelming amount of data and to give laboratories flexibility in how they are required to report such data.

"Private payor" is a term that is defined in the law, yet laboratories will need additional guidance from CMS about how to distinguish payors when reporting. The definition of a "private payor" includes "a health insurance issuer" and a "group health plan," as those terms are defined in the Public Health Service Act. A "health insurance issuer" is "an insurance company, insurance service, or insurance organization (including an [HMO]) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance…". A "group health plan" is an employee welfare benefit plan, to the extent that the plan provides medical care to employees and their dependents directly or through insurance, reimbursement, or otherwise.[11] A "health insurance issuer" often is an enormous corporation that is licensed in many or all states to sell health insurance coverage through a variety of products.

Notwithstanding the statutory definition noted above, CMS will need to define exactly how "private payor" is to be understood in this context to provide clear instruction to applicable laboratories about how to assemble and report data. For example, laboratories do not have a "United Healthcare" rate for a given laboratory test – United Healthcare pays thousands of different rates for a test, based on the plan, location, place of service, and health care provider. Similar complexity will arise with Medicare Advantage and Medicaid managed care organization plans. Adding to the complexity of the task of determining which rates applicable laboratories will report to CMS is the fact that laboratories that are out-of-network are paid varying rates, sometimes by the same payor in the same year.[12]

CMS also will need to be clear about what constitutes a payment rate. In most cases, the rates that private payors set for laboratory tests account not only for the amount that the health insurer will pay, but also the copayment that a patient will pay to the laboratory. For example, when a private payor rate for a laboratory test is $100 and there is a 20 percent coinsurance

[11] Public Health Service Act § 2719 (42 U.S.C. § 300gg-91). *See* Social Security Act § 1834A(a)(8)(A) (42 U.S.C. § 1395m-1(a)(8)(A)).

[12] When a laboratory is out-of-network, it may bill a payor the charge for a test and be paid just a fraction of that amount by the payor, based on the payor's policy for determining its liability for out-of-network services without regard for any negotiation with the laboratory about the rate for a specific test. Under such circumstances, the payor may allow the laboratory to collect the remainder of its charge from the patient as the patient's cost-sharing for the out-of-network test. The total amount allowed by the payor and due to the laboratory, and not just the amount paid by the payor, is what is relevant and should be reported.

liability, a laboratory counts on a private payor to pay $80 and on the patient to pay $20. Patients also sometimes have deductibles to meet, meaning that a private payor may be involved in the rate-setting for a particular service but not involved in payment if the deductible exceeds the rate set by the payor for the test. In addition, some patients may have multiple payors on a claim (including a primary and a secondary payor) that may have different rates allowed for the same claim.

CMS's definitions of "private payor rates" and volumes should lead to a reporting system that yields the most complete information for the agency about how laboratories are compensated for their services to support calculation of accurate Medicare rates and that places the least burden possible on the reporting laboratories.

- ***Recommendation: To ensure consistency among reported rates, laboratories should report the final total approved payment rates for covered services during the reporting period, excluding information on those services for which appeals are outstanding and for which final rates are not yet determined. The approved payment rate should be the total "Allowed Amount" paid by a private plan, as that term is understood in the context of HIPAA 5010 transactions, including any copayments, coinsurance, deductible amounts, and other patient cost-sharing.***

3. Length of the data collection period. CMS should require laboratories to report as much data as the agency needs to calculate accurate market-based Medicare payment rates, but it should not require laboratories to report any more data than is necessary. For example, one calendar quarter's worth of private payor data may be sufficient for the agency to derive a Medicare rate reflecting the private payor market rate for a high-volume, broadly-distributed laboratory test such as a complete blood count ("CBC"). This is one of the most commonly performed laboratory tests, so one quarter's worth of data would yield a sufficient volume and cross-section of claims to develop an accurate Medicare payment rate, as contemplated by the law. For other tests that are performed more rarely, the volume in a given quarter may be lower, and data from one quarter may not be sufficient to reflect private market rates accurately. When members of the undersigned organizations of this letter evaluated their payment experience for six months of test claims, compared with 12 months of test claims, the resulting median payment amounts generally were consistent with each other. Therefore, we believe CMS can strike the right balance for all tests, regardless of volume or frequency, by requiring laboratories to report data for tests furnished in a six-month period.

- ***Recommendation: The first data collection period should be six months, and it should cover the first six months of 2015. We believe future data collection periods also should span six months, although the initial experience may indicate the desirability of some change. CMS should establish reporting periods via notice-and-comment rulemaking.***

4. Time period for reporting. The text of the statute says that an applicable laboratory shall report the rate and test volume at each rate "for each clinical diagnostic

laboratory test that the laboratory furnishes during [the data collection] period".[13] While the data collection period will have a defined beginning and end during which tests are furnished (*i.e.*, the date of service of the laboratory test), it can take months for payors to adjudicate a claim fully and to determine the rate that ultimately is allowed for a given test. Thus, the date of the service of the laboratory test may be within the data reporting period, but final adjudication of the allowed rate may fall on a date well after the end of the reporting period. The lag in payment is particularly pronounced for out-of-network laboratories that do not have contracts with a given payor to which they submit claims.

In order to report accurate rates and test volumes to CMS, laboratories will need time to collect fully adjudicated payments between the end of a data reporting period and the date on which payment arrays must be reported to the agency. Laboratories also will require some time after payments are made to gather all relevant data and prepare an array for reporting.

- ***Recommendation: Applicable laboratories should report private payor payment rates for tests with a date of service that falls within the six month data reporting period and that have been fully adjudicated within six months after the end of the reporting period. Thus, CMS should leave at least six months between the end of the data reporting period and the end of a follow-up period that allows laboratories adequate time to collect payment data so that they may submit accurate payment rates and volumes to CMS. This also would allow a lab to factor into its reported rates any volume-based discounts, rebates, and price concessions. Laboratories should have an additional sixty days following the conclusion of the follow-up period to organize, review, verify, and report their data array.***

A schematic of this recommended timeline is included as an attachment to this letter.

5. Mechanism for reporting data. Laboratories will be required in some cases to report thousands of private payor rates to CMS, and CMS will need to accept a huge amount of data from hundreds or even thousands of laboratories. CMS must develop a reporting mechanism that is workable for many different kinds of laboratories (that may have very different information technology capabilities and resources), that is secure, that is user-friendly, and that allows CMS to organize the data to derive accurate Medicare payment rates. Ideally, this should be through an Internet reporting portal. (CMS has experience with this for reporting drug payment rates under the Medicaid drug rebate law. The volume of data required to be reported in this instance is substantially greater than that reported for Medicaid rebates.) CMS should consider convening a meeting of its information technology experts with those working in the laboratory industry to develop plans for an easy-to-use and reliable reporting mechanism that will be effective for the agency and for reporting laboratories alike.

- ***Recommendation: An electronic reporting mechanism, such as an internet-based portal, should be established for laboratories to report their private payor***

[13] Social Security Act § 1834A(a)(1) (42 U.S.C. § 1395m-1(a)(1)).

data. CMS should provide opportunities for laboratories to test their rate-reporting capabilities in an "end-to-end" fashion and for CMS to test its information technology infrastructure prior to the actual reporting date.

6. Confidentiality of data. Congress clearly intended for CMS to guard the confidentiality of data reported by applicable laboratories and for such data to be disclosed in a manner that may identify a laboratory or a payor only in very limited situations. The laboratory industry seeks assurance from CMS that disclosures made "as the Secretary determines to be necessary to carry out" the law will be arrived at judiciously and that no more identifiable data will be revealed than is truly required.

- ***Recommendation: To maintain the integrity and legitimacy of the reporting process, CMS should apprise the public of the situations in which the Secretary would find such disclosures to be necessary and to set a high bar for disclosing information that might reveal the identity of a laboratory and/or a private payor.***

II. MEDICARE PAYMENT RATE DEVELOPMENT

Just as important as how CMS collects data on private payor data from applicable laboratories is how it uses the data to arrive at Medicare rates that will apply until the next data collection cycle. It is crucial that the Medicare payment rates are developed accurately and transparently to ensure appropriate Medicare payments and because many other payors (including many Medicaid programs) base their rates on Medicare rates.

A. The Law

For a clinical laboratory test furnished on or after January 1, 2017 (that is not a new test or an ADLT), the Medicare payment amount is to be the "weighted median" for the most recent data collection period. The "weighted median" payment for a laboratory test is to be calculated by "arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory."[14] Once a rate is established, it is to remain in effect until the year following the next data collection period, and it "shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment)".[15] Also, for the years 2017 through 2019, the amount of a reduction in the Medicare rate (if any) shall not exceed 10 percent from the prior year's rate, and for 2020 through 2022, any reduction shall not exceed 15 percent from the prior year's rate.

An ADLT will be paid "during an initial period of three quarters" at the "actual list charge," which is the publicly-available rate on the first day that a test is available for purchase by a private payor. After the "initial period of three quarters," Medicare will pay a "weighted median" of the private payor rates the laboratory reported during the "second quarter of the

[14] Social Security Act § 1834A(b)(2) (42 U.S.C. § 1395m-1(b)(2)).

[15] Social Security Act § 1834A(b)(4) (42 U.S.C. § 1395m-1(b)(4)).

initial period." When the actual list charge is more than 130 percent of the weighted median rate, CMS may recoup the difference between the two rates.[16]

For new tests that are not ADLTs, Medicare payment shall be determined using crosswalking or gapfilling. Additionally, the statute requires CMS to provide a detailed and transparent explanation regarding the basis for payment rates for these tests, what criteria were applied, and how. The law also calls for CMS to establish an "expert outside advisory panel," subject to the Federal Advisory Committee Act, to provide input on payment rates, factors to consider for coverage and payment processes, and any other issues raised under the CLFS reform law. The size of the panel is not specified. The panel is to be assembled no later than July 1, 2015, and it is to consist of a cross section of individuals with experience in laboratory science, health economics, molecular pathology, clinical laboratory tests, and similar fields. This panel will not take the place of CMS's annual clinical laboratory meeting.

B. Issues, Questions, and Suggestions

1. Development of weighted median rates. The text of the law does not provide CMS with much direction about how to determine weighted median rates for each test. When CMS proposes a method for developing each weighted median, we ask that the agency provide the public with a detailed explanation of how it will array all of the private payor data for each individual laboratory test to arrive at the weighted median.

2. Transparency and re-review of published rates. We hope that the data reporting mechanism that CMS develops will be efficient and reliable and that the agency will be capable of accepting and storing the enormous amount of data that applicable laboratories will report to it. Given the large amount of data, it is reasonable to expect that, from time to time, errors will occur due to information management challenges and/or inaccurate calculations. While the law precludes administrative or judicial review of payment amounts,[17] it does not prohibit CMS from establishing a process to accept requests for re-review of proposed rates. Such systems already exist in other contexts in the Medicare program (*e.g.*, PFS and OPPS).

- ***Recommendation: We urge CMS to ensure that there is sufficient transparency in the rate-calculation and rate-setting processes. CMS should allow stakeholders to review preliminary payment rates prior to their effective date and request that CMS review potentially inaccurate rates. To facilitate this step, CMS should publish preliminary payment rates at least three months prior to their effective date.***

3. Adjustments to rates. The statute states that, once established and until the year following the next data collection period, weighted median rates shall not be subject to adjustments such as geographic adjustments, budget neutrality adjustments, annual updates, or

[16] Social Security Act § 1834A(d) (42 U.S.C. § 1395m-1(d)).

[17] *See* Social Security Act § 1834A(h)(1) (42 U.S.C. § 1395m-1(h)(1)). This refers to formal reviews by an administrative law judge and to review of a final administrative decision in a federal court.

"other adjustments." It seems clear that these rates would not be subject to the multifactor productivity adjustment added by the Section 3401(l) of the Affordable Care Act; it is not named specifically in the law, yet it would be fairly encompassed by "other adjustments." We ask for confirmation of this interpretation.

- ***Recommendation: CMS should confirm that the rates established under Section 216 of PAMA will not be adjusted by the multi-factor productivity adjustment added by Section 3401(l) of the Affordable Care Act.***

4. "Initial period" for new ADLTs. Congress intended for payment during an "initial period of three quarters" to mean the period when a test first is covered and payable by a Medicare contractor. Congress clearly contemplated that laboratories would be paid by Medicare for new ADLTs during this period or it would not have included the possibility of recoupment when payment based on actual list charges exceeds 130 percent of the rate established on the basis of private payor data.

As set forth in the law, the payment rate during this initial period will be based upon the publicly-available actual list charge offered by the laboratory for the test on the first date on which the test is commercially available for coverage and payment by private payors.

Laboratories are required to report private payor data for the initial period for new ADLTs no later than the end of the second quarter of the initial period. The statute is silent, however, on the time period that such initial report should cover. Insofar as there may be fewer payors covering and paying for a new ADLT during this period, it would be appropriate for the reporting period to be longer than just the first quarter of the initial period of Medicare coverage and payment. If there are private payor data that reach a certain volume threshold from the quarter before the first quarter of Medicare coverage and payment, these data should be included to allow for at least six months of data collection.

- ***Recommendation: For new ADLTs, the "initial period of three quarters" for rate reporting that is referenced in the statute should begin once a Medicare administrative contractor ("MAC") determines that an ADLT is covered by Medicare and a unique Healthcare Common Procedure Coding System ("HCPCS") code has been issued to identify the test. The reporting period should include the first quarter after Medicare coverage and payment has commenced, and if there are sufficient data from the quarter prior to commencement of Medicare coverage and payment, those data should be included, as well.***

5. Recoupment. CMS may recoup funds from an applicable laboratory if it determines that the actual list charge it paid to a laboratory for a new ADLT in the initial period exceeds 130 percent of the calculated weighted median rate. We assume that, in such cases, CMS would recoup the difference between the actual list charge and 130 percent of the weighted median. CMS should advise laboratories about how it will recoup such funds. CMS's process also should include a mechanism for a laboratory to dispute any such recoupment before the recoupment occurs.

- ***Recommendation: CMS should provide laboratories with guidance regarding the recoupment process, confirming that the amount of excess payments to be recouped (if any) is the difference between the actual list charge and 130 percent of the weighted median.***

6. ADLTs that meet similar criteria to those established in statute. CMS should establish criteria under which a test furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory can be classified as an ADLT if it is similar to those mentioned in the statute.

7. Process of ADLT determination. MACs should have the authority to determine whether a test meets criteria for classification as an ADLT, and this determination could be made at the time of establishing Medicare coverage and payment. Pursuant to section 1834A(e)(1) of the Social Security Act, a new test determined to be an ADLT would be assigned a temporary HCPCS code.

- ***Recommendation: CMS should consider establishing a process whereby laboratories may request that either CMS or the MACs may determine if a test is eligible to be classified as an ADLT for purposes of Section 216 of PAMA.***

8. New tests that are not ADLTs. CMS is to use crosswalking or gapfilling for new tests that are not ADLTs. The recent gapfilling exercise for molecular diagnostic codes was challenging for laboratories, both because of data problems between the MACs and CMS and because of inadequate transparency in the process and gapfilling results. We are heartened that the statute includes language directing CMS to explain how it arrived at each payment rate for each new test that is not an ADLT and what factors it considered in developing the payment rate, and that CMS is to consider recommendations on payment rates from the newly-created expert advisory panel. We urge CMS to provide more than simple, cursory explanations of its rate determinations and to draw upon the resources it has in the expert advisory panel to consider carefully how new tests are paid.

9. Expert advisory panel. The expert advisory panel is to be assembled before applicable laboratories begin reporting private payor data to CMS. It is clear that Congress intended this panel to lend its expertise and advice to CMS on the assignment of payment rates to new tests through the crosswalk or gapfill process and on the reporting process and structure in general. It is our hope that CMS will give serious consideration to the panel's advice and that it will make clear to the public how it is using the panel to develop coverage and payment policies. We are convinced that to derive the most value from the panel, CMS should include on it those individuals who have recent direct experience in the clinical laboratory industry. Individuals with this real-world experience can shed light on how policies can be operationalized by clinical laboratories and not be at odds with the way that laboratories actually function. The statute leaves CMS discretion to include experts on the panel beyond those suggested by the statute, and we strongly urge CMS to include those with technical expertise in developing, validating, and performing clinical laboratory tests; patient representatives; clinicians who use clinical laboratory test results; laboratorians; and individuals with expertise in pharmacoeconomics and/or health technology assessments. The panel's membership also should reflect the laboratory industry's geographic and size diversity and the viewpoints of independent clinical

laboratories, hospital laboratories, and physician office laboratories. CMS should take full advantage of the resources it will have available in the expert advisory panel and draw upon the panel's members for advice on how new tests should be paid.

To maximize the value of the panel, CMS must consider carefully when during the year the panel should convene and the agendas for each of meeting. We hope to have further opportunities to interact with CMS to explore fully the issues related to the composition and functions of the expert panel.

- ***Recommendation: CMS should ensure that at least some panel members have recent industry experience with clinical laboratory operations, commercial test development, and diagnostics reimbursement, and it also should account for patient and clinician perspectives. Stakeholders should be afforded an opportunity to provide input on the advisory panel's charter, role, processes, and meeting agendas.***

III. CODING

A. The Law

CMS is required to develop temporary HCPCS codes for new ADLTs and new FDA-cleared or –approved tests that will be effective until permanent HCPCS codes are established (but not longer than two years). For existing ADLTs and FDA-cleared or –approved test that are paid for by Medicare and that do not have uniquely-assigned HCPCS codes, CMS is to assign unique HCPCS codes and publicly report payment rates. The statute also allows a laboratory to request a "unique identifier" for an ADLT or FDA-cleared or –approved test "for purposes of tracking and monitoring".[18]

B. Issues, Questions, and Suggestions

1. Existing ADLTs or FDA-cleared or approved tests without unique HCPCS codes. CMS should develop a process through subregulatory guidance to issue, as soon as possible, unique HCPCS codes and publish the payment rates for existing ADLTs and clinical laboratory tests that were cleared or approved by the FDA and paid by Medicare as of the date of enactment under a miscellaneous code or otherwise not reported under a uniquely assigned code (*e.g.*, a non-specific method code that does not describe a specific ADLT or FDA-cleared or –approved test). CMS should allow laboratories and manufacturers to submit requests for unique HCPCS codes through an expedited process. This will facilitate data collection for rate-setting by having a common coding system to report payments from private payors in 2015.

- ***Recommendation: CMS should develop a process as soon as possible through subregulatory guidance to issue unique HCPCS codes and publish the payment rates for existing ADLTs and existing clinical laboratory tests that were cleared or approved by the FDA and paid by Medicare as of the date of enactment***

[18] Social Security Act § 1834A(e) (42 U.S.C. § 1395m-1(e)).

under miscellaneous codes or otherwise not reported under uniquely-assigned codes.

2. Expedited code assignment for new ADLTs and new FDA-cleared or approved tests. The statute requires CMS to adopt temporary HCPCS codes to identify new advanced diagnostic laboratory tests and new tests that are cleared or approved by the FDA. CMS should develop a process for expedited application, consideration, and approval of HCPCS codes for these tests; each code should be unique to a test and the codes should not be the "not otherwise classified" codes currently in use. Further, CMS should allow laboratories and manufacturers to submit requests on a quarterly basis for determination and issuance of new codes in a four month timeframe consistent with the timeframe by which CMS evaluates applications for pass-through codes and payment, assigning codes as necessary, under the Outpatient Prospective Payment System (*e.g.*, applications submitted by March 1 would result in codes effective July 1).

- ***Recommendation: CMS should establish an expedited code establishment process that includes quarterly review of tests and issuance of unique HCPCS codes to describe tests.***

3. Unique identifiers. The statute authorizes CMS to adopt a process whereby a laboratory or manufacturer offering an ADLT or an FDA-cleared or approved test may request a unique identifier for the test. The statute authorizes CMS to adopt such unique identifiers by means of a HCPCS code, a modifier, or other means. Insofar as currently-covered and new ADLTs and FDA-cleared or -approved tests would be assigned unique HCPCS codes under the provisions discussed above, it would appear appropriate that the unique identifiers should be uniquely assigned HCPCS codes rather than modifiers or other designators that are not entered in the code field of a claim form.

If a CPT code is assigned that is less granular than the HCPCS code and that does not identify the test uniquely, a laboratory or manufacturer should be able to request a unique test identifier for the test. Such a request could be fulfilled by reviving the expired HCPCS code or through adoption of some other unique test identifier. This would ensure that MACs and other payors that adopt coverage and/or payment policies specific to the ADLT or the FDA-cleared or –approved test would be able to continue to implement such policies without pending claims for manual adjudication.

- ***Recommendation: CMS should consider using HCPCS codes as the "unique identifier" contemplated under Section 216 of PAMA. In addition, CMS should substitute granular HCPCS codes for more general CPT codes when appropriate.***

IV. COVERAGE

A. The Law

The CLFS reform law establishes parameters for how MACs may establish coverage policies through local coverage determinations ("LCDs") on or after January 1, 2015. It also

permits CMS to designate up to four MACs to establish coverage policies, or both to establish coverage policies and to process claims for payment, for clinical diagnostic laboratory tests.

B. Issues, Questions, and Suggestions

1. Local Coverage Determinations. We are encouraged that the law ensures that LCDs henceforth are to be developed according to the process already spelled out in Section 1869 of the Social Security Act and implementing regulations. Coverage policies for clinical diagnostic laboratory tests have been issued recently through less formal processes, such as articles, without following the existing notice-and-comment requirements of the Social Security Act. We would like to hear from CMS how the agency intends to enforce this section of the law.

2. Medicare Administrative Contractors. We still are studying the issues around consolidating coverage or coverage and payment processing in a small group of MACs. Of utmost importance to us is the fairness and transparency of coverage and payment processes, rather than the number of MACs that are involved.

V. IMPLEMENTATION

The timeline for implementing the CLFS reform provisions of the Protecting Access to Medicare Act of 2014 is extremely tight, given the complexity of the provisions and the magnitude of data involved. The expert advisory panel is to be assembled and functioning by July 1, 2015, and CMS is to issue regulations regarding payment rate reporting no later than June 30, 2015. Actual data reporting is to begin January 1, 2016, and CMS must calculate weighted medians for each individual test in time for them to take effect on January 1, 2017.

We are concerned about the short amount of time – just six months – between the date by which CMS must issue final regulations on data reporting and the time when the agency may require applicable laboratories to begin reporting private payor data. Congress gave CMS the authority to determine when each applicable laboratory needs to report private payor data, so long as the date is not before January 1, 2016. It will take laboratories time to understand and operationalize what CMS includes in a final rule, regardless of a laboratory's size. Larger laboratories may be challenged by the sheer volume of data they must collect and report for each payor, plan, and test code in a very short period of time, while smaller and medium-sized laboratories may be at a disadvantage from not having information technology, coding, and/or billing resources that are equal to the task. All laboratories will need a number of months to develop internal data collection systems that meet the requirements of the final rule, once it is issued.

We also are sensitive to the fact that CMS will need adequate time to accept, organize, analyze, and use the data that applicable laboratories report and that it must have calculated all of the weighted medians for each clinical laboratory test in time for the new rates to take effect January 1, 2017. From the agency's perspective, this may weigh against setting a date that is too far into 2016 by which applicable laboratories must report data. The laboratory industry wants CMS to have an adequate amount of time to organize the data and to calculate accurate weighted medians. It is not in our interest for CMS to have to rush through the process of setting new payment rates for more than one thousand clinical laboratory tests.

We would like to work with CMS to find a balance between leaving an adequate amount of time between the issuance of the final rule and the date by which private payor data must be reported on the one hand, and leaving enough time between data reporting and the effective dates of the new Medicare rates on the other hand, so that the agency can calculate accurate rates. We hope to continue our dialogue with the agency about this point to develop a solution that is workable for all parties.

We agree with CMS that given the complexity of the new law and the limited timeframe until publication of the CY 2015 PFS proposed rule, implementation of Section 216 of PAMA will require its own rulemaking. However, the upcoming CY 2015 CLFS public meeting presents an excellent opportunity for CMS and stakeholders to continue a constructive dialogue about implementation.

We hope that CMS will give serious consideration to conducting a test, perhaps one that involves limited rate reporting and limited Medicare reimbursement calculations, to ensure that both laboratories and the agency are ready to implement the process fully and to allow the agency and applicable laboratories the opportunity to learn from what worked and what did not work. Such testing also could help the agency determine how long it will take to accept and organize reported data, the steps involved in calculating and verifying the accuracy of the weighted median rates and the length of time to do so, and the unanticipated challenges of the overall private payor data reporting and Medicare reimbursement rate-setting program. It also would provide CMS, applicable laboratories, and other interested stakeholders an opportunity to collaborate further on how to improve the reporting program.

- ***Recommendation: Given how soon laboratories will have to collect data to report to CMS early in 2016, it is important for the agency to proceed with the regulatory implementation process as soon as possible. CMS also should formally withdraw the regulation that appears at 42 C.F.R. § 414.511 regarding adjusting payment rates on the CLFS based on technological changes, which relied on a statutory provision that Congress eliminated in PAMA.***

- ***Recommendation: CMS should consider establishing a reporting test, possibly limited to a small yet statistically appropriate number of codes and laboratories, and calculate "draft" weighted median Medicare rates so that applicable laboratories can review their ability to collect, array, and submit rates to the agency and so that CMS can verify its ability to collect data and calculate correct payment rates, before the reporting system is used for all clinical laboratory test rates.***

* * * * *

We thank you again for your willingness to work collaboratively with the clinical laboratory industry and with other interested stakeholders toward successful implementation of Section 216 of PAMA. We look forward to a constructive ongoing dialogue with CMS, and we welcome your thoughts and questions.

Sincerely,

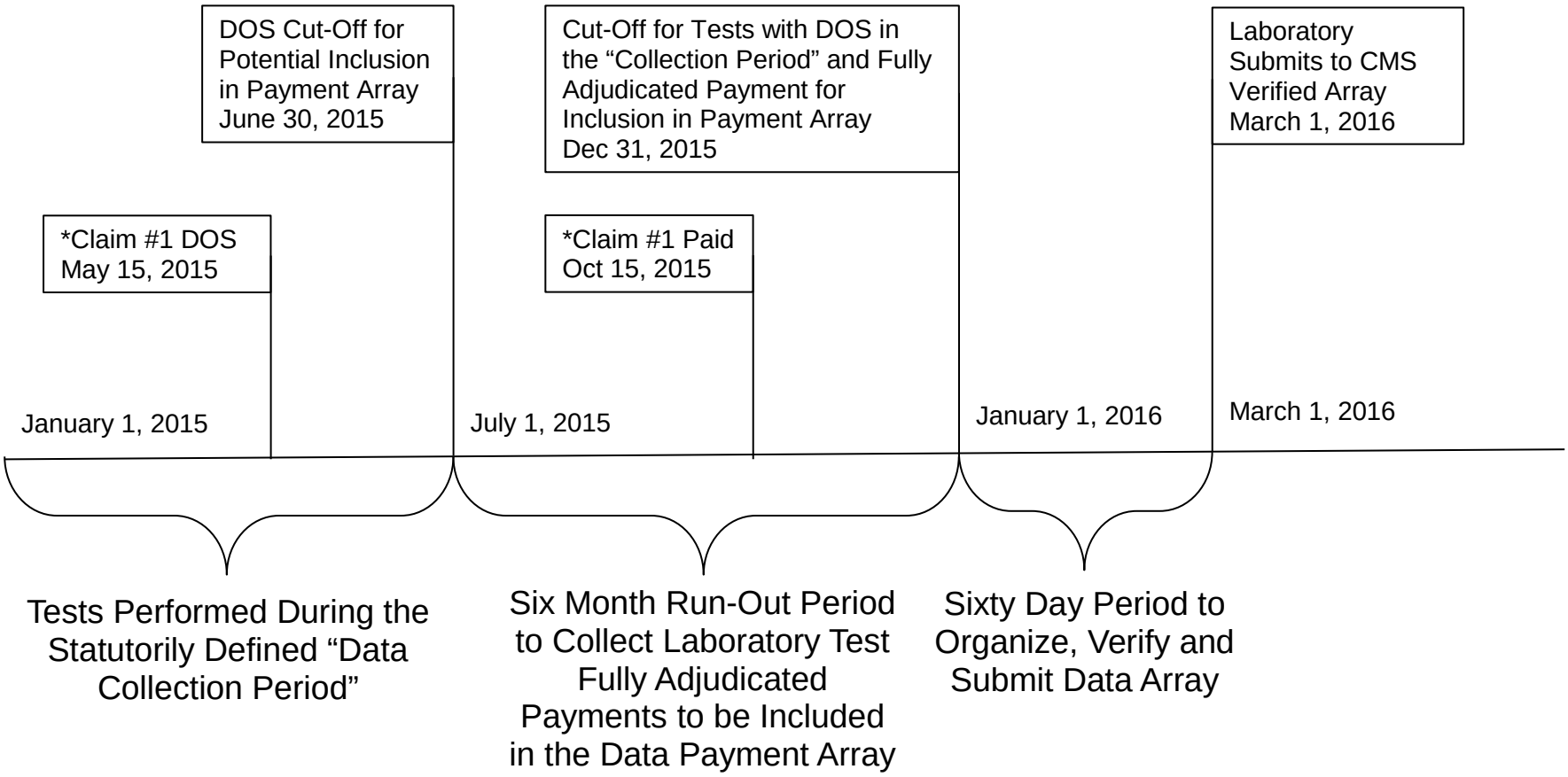
Alan Mertz, President
American Clinical Laboratory Association

Donald May, Executive Vice President
AdvaMedDx

John Hanna, Chair, Reimbursement & Policy Workgroup
Coalition for 21st Century Medicine

cc: Sean Cavanaugh
Marc Hartstein

Data Array Collection & Submission Timeline



*Claim #1 is an illustrative example of a diagnostic test that is performed with a date of service (DOS) of May 15, 2015, and is fully adjudicated and paid on October 15, 2015. Since Claim #1 is fully adjudicated within the six month run-out period, it is included in the payment data array reported to CMS. If Claim #1 was adjudicated after December 31, 2015, it would not be reported in the payment data array.