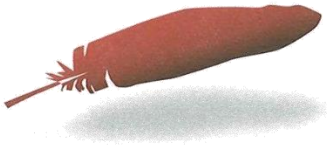
National Indian Health Board



Submitted via: http://www.regulations.gov

November 24, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Comment on CMS-1621-P

Dear Centers for Medicare & Medicaid Services:

On behalf of the National Indian Health Board (NIHB), I write to comment on the proposed rule entitled: "Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System." Established in 1972, the NIHB is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all American Indians and Alaska Natives (AI/ANs). The NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service (IHS) Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with the NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-Determination and Education Assistance, or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.

We recognize that the CMS has been tasked with a large amount of work to accomplish the implementation of this reimbursement reform proposed rule in a very short amount of time. However, we encourage CMS to be cautious in its efforts and take into account all stakeholders, including Indian Tribes, as it issues its final rule. Congress has recognized that "[f]ederal health services to maintain and improve the health of the Indians are consonant with and required by the Federal Government's historical and unique legal relationship with, and resulting responsibility to, the American Indian people."[1] The federal trust responsibility and laws enacted pursuant thereto provide ample authority for the federal agencies of the Executive Department to design, implement and tailor federal programs in a manner that recognizes and supports the unique government to government relationship between sovereign Tribal governments and the United States.

[1] 25 U.S.C. § 1601(1).

We agree with many of the comments made by the American Clinical Laboratory Association (Attachment 1). For example, the definition of what the Protecting Access to Medicare Act of 2014 (PAMA) considers an "applicable laboratory" must be broad enough to encompass many types of laboratories that perform various testing services paid for by Medicare, including those within an Indian Health Service clinic, Tribal health clinic, or Urban Indian clinic (I/T/U).

In addition, CMS must make it clear to applicable laboratories what it considers to be a "payment rate." In most cases, the rate that a private payor sets for a laboratory test accounts not only for the amount that the private payor will pay, but also any copayment from a patient. However, in the I/T/U system, there is no cost-sharing or copayments from a patient. It is extremely important that CMS take these special AI/AN protections into account when issuing the final rule. Medicare is an important source of third party revenue for I/T/Us because of severe underfunding to meet basic health care needs in Indian Country.

The ACLA suggests that CMS establish an electronic reporting mechanism, such as an internet based portal, for laboratories to use to report their payor rates. While we think that this is a good idea, in Indian Country, not only do the I/T/Us not have the necessary tools (wifi, internet, hardware, etc.), but the patients typically have less resources. These barriers must be taken into account and a paper reporting exception shall be granted for I/T/Us as Indian Country generally does not have the means or ability to complete electronic reporting requirements.

We would also like to request Tribal consultation on the final proposed rule as it is of the utmost importance that the Indian Health Service and Medicare units within CMS conduct consultation for coordination, so that the federal agencies are coordinated in their efforts. This is consistent with the President's consultation policy as outlined in Executive Order 13175 of November 6, 2000 and confirmed in the memorandum of November 5, 2009.

Thank you for considering these comments. Please do not hesitate to contact us for further information.

Sincerely,

Lester Secatero, Chair
The National Indian Health Board

Cc: Kitty Marx, Director, CMS Division of Tribal Affairs

Attachment 1: Statement of the American Clinical Laboratory Association on Clinical Laboratory – Related Provisions in the Protecting Access to Medicare Act of 2014.

STATEMENT OF THE
AMERICAN CLINICAL LABORATORY ASSOCIATION
ON CLINICAL LABORATORY-RELATED PROVISIONS IN THE
PROTECTING ACCESS TO MEDICARE ACT OF 2014

American Clinical Laboratory Association

The American Clinical Laboratory Association ("ACLA") is pleased to submit its recommendations to the Centers for Medicare & Medicaid Services ("CMS") on various aspects of implementation of Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), which modifies the Medicare reimbursement rate methodology under the Clinical Laboratory Fee Schedule ("CLFS") for the first time in about three decades.[1] ACLA is a trade association representing national, regional, and esoteric laboratories that perform millions of tests each year that are paid for under the CLFS. The way in which CMS proceeds in implementing this reimbursement reform provision and the choices it makes will have a major impact on ACLA members.

Congress has directed CMS to accomplish a great deal in a very short period of time. By June 30, 2015, the agency must develop, propose, refine, and finalize a method for laboratories to report each reimbursement rate and volume for each test code on the CLFS for each private payor and develop its own method for calculating the weighted medians from that data that will become the applicable Medicare rates. To do so, CMS must develop or clarify definitions of several key terms, determine when private payor rates must be reported and for what timeframe, build a technology platform capable of accepting millions of discrete pieces of data, and establish coding processes for certain new tests, among other tasks. All of this must be completed in time to give laboratories clear direction about what data to report and how to do so, and with enough lead time for laboratories to develop their own internal systems to compile and report the data.

[1] Pub. L. 113-93, Sec. 216, adding Sec. 1834A to the Social Security Act ("the Act") (codified at 42 U.S.C. § 1395m-1(2014)).

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The way in which CMS defines the parameters, participants, methods, and timeframes for rate and volume reporting can have a substantial impact on the rates that the Medicare program pays for clinical laboratory tests. It also has the potential to have an impact on other payors' rates, as many private payors and state Medicaid programs base their reimbursement rates on Medicare rates.

This is a tremendously complex undertaking, and ACLA and its members are prepared to continue to work with CMS to ensure that implementation proceeds smoothly and in a manner that works for CMS and clinical laboratories alike. We urge CMS to work collaboratively with stakeholders in the coming months as the agency develops definitions, standards, processes and procedures to implement Section 216 of PAMA.

Our statement today focuses on reporting payment rates and volumes for clinical laboratory tests and on Medicare payment rate development. While our statement concentrates primarily on rate and volume reporting, we will discuss additional issues in our written comments. In addition, ACLA has worked closely with AdvaMedDx and the Coalition for 21st Century Medicine, and we have reached consensus on recommendations in many key areas, which will also be reflected in our written submission.

I. BACKGROUND ON RATE AND VOLUME REPORTING AND RATE-SETTING

Beginning January 1, 2016 and generally every three years thereafter, each "applicable laboratory" is to report to CMS information, with respect to a defined data collection period, about the payment rates paid by each private payor for each test code on the CLFS and about the volumes for each test paid at each of those rates.[2] An "applicable laboratory" is a laboratory that receives

[2] The timetable and data reported differs for "Advanced Diagnostic Laboratory Tests" ("ADLTs"), which are tests offered or sold only by one laboratory and that meet certain other criteria. Rate and volume reporting is yearly for ADLTs.

a majority of its Medicare revenue under the CLFS, the Medicare Physician Fee Schedule ("PFS"), or new Sec. 1834A of the Act.[3] Neither the term "laboratory" nor the term "revenue" is defined in PAMA or in the Act. A "private payor" is a health insurance issuer, a group health plan, a Medicare Advantage plan, or a Medicaid managed care organization.[4]

Once "applicable laboratories" have reported this data to CMS, CMS is to develop a "weighted median" based on the data, which for most tests will become the Medicare payment rate for the following three years. (Rates for ADLTs are to be in effect for one year, as reporting and rate-setting will occur annually for this subset of tests.)

II. REPORTING

A. "Applicable Laboratory"

Section 216 of PAMA gives CMS some direction about what it considers an "applicable laboratory," but the agency will have to define the parameters of that term further. In order to reflect true market rates for laboratory services, the definition must be broad enough to encompass the many types of laboratories that perform testing services paid for by Medicare. It is logical that most independent clinical laboratories would be included in the definition of "applicable laboratory," but other types of laboratories also fit the definition.

Congress's intent with respect to the private payor rate reporting requirements in Section 216 of PAMA was to ensure that Medicare rates for clinical laboratory services reflect private market rates and that all sectors of the laboratory market are represented in the calculation of the weighted median, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the CLFS. The plain text of the statute reflects

[3] Social Security Act § 1834A(a)(2) (42 U.S.C. § 1395m-1(a)(2)).
[4] Social Security Act § 1834A(a)(8) (42 U.S.C. § 1395m-1(a)(8)).

this intent, as does a colloquy on the Senate floor between Sen. Orrin Hatch (R-UT), the Ranking Member of the Senate Finance Committee, and Sen. Richard Burr (R-NC).[5]

It is appropriate for hospital outreach laboratories to be included in the ambit of the definition of "applicable laboratory," and they should be required to report private payor rates to CMS. In the text of the law, an "applicable laboratory" is a "laboratory" that receives the majority of its Medicare revenues under the CLFS, the PFS, or new Section 1834A of the Act. When a hospital laboratory serves non-patients and hospital outpatients (when those services are not bundled in an APC payment), and a majority of the laboratory's separately-identifiable Medicare revenues are derived from the CLFS, the PFS, or Section 1834A of the Act, then the hospital laboratory should be considered an "applicable laboratory."

Similarly, it may be appropriate in some instances for physician office laboratories to be encompassed by the term "applicable laboratory." Certain physician offices 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. Some physician office laboratories also perform more complex tests, as well. Categorical exclusion of physician office laboratories would deny CMS important information about a significant market sector. At the same time, we recognize that, as complex as rate reporting is bound to be, the burden on some smaller physician office laboratories could outweigh the information gleaned from them. CMS was given the authority to

[5] Sen. Richard Burr (R-NC) is a member of the Senate Finance Committee and Sen. Orrin Hatch (R-UT), Ranking Member of that committee. On the floor of the U.S. Senate, 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 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." *See* 160 Cong. Rec. S2860 (daily ed. May 8, 2014).

establish a "low-volume or low-expenditure" threshold, and it may be appropriate to exercise that authority with respect to some physician office laboratories.

In sum, ACLA urges CMS to define the term "applicable laboratory" in a way that reflects the wide variety of entities that receive payment for lab tests under the CLFS and that allows CMS to account for the full spectrum of private payor rates for laboratory tests.

B. Private Payor Rates and Volumes

1. The Law

The law requires each applicable laboratory to report the payment rate paid by each private payor for each test during the defined reporting period, and each applicable laboratory also must report the volume for each such payor for each test.[6] 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, it is to report each such payment rate and the volume for the test at each such rate.[7]

2. Payment Rate

CMS must make it clear to applicable laboratories what it considers to be a "payment rate." In most cases, the rate that a private payor sets for a laboratory test accounts not only for the amount that the private payor will pay, but also any copayment from a patient. Patients also sometimes have deductibles to meet, meaning that a private payor may be involved in rate-setting for a particular service but not involved in the payment. To ensure consistency among reported rates across applicable laboratories, applicable laboratories should report the final total approved payment rates for covered services during the reporting period – the total "allowed amount" paid

[6] Social Security Act § 1834A(a)(3) (42 U.S.C. § 1395m-1(a)(3)).
[7] Social Security Act § 1834A(a)(6) (42 U.S.C. § 1395m-1(a)(6)).

by the private payor, as that term is used in the context of HIPAA 5010 transactions, including any copayments, coinsurance, deductible amounts, and other patient cost-sharing.

3. Complexity of the Reporting Exercise

In discussing the reporting requirements with our members over the past several weeks, we have been reminded of the vast amount of data that this reporting will yield and the complexity of CMS accepting and organizing the data and using it properly to calculate accurate weighted medians. ACLA's members also have considered the information technology resources they will have to expend in order to collect, organize, duplicate, verify, and report the data to CMS.

The challenges that applicable laboratories are likely to face have been foreshadowed by laboratories' experience reporting private payor rates to the California Medicaid program ("Medi-Cal"). There, labs were required to report rates for about 400 tests (only about a third of the tests included on the CLFS), and for at least their top five payors by volume for each test. Many labs that participate in Medi-Cal had difficulty assembling the required information in time to meet the first reporting deadline, and the program was forced to extend the reporting deadline by three months so that laboratories could comply. It is conceivable that the same thing could happen in the context of this private payor rate and volume reporting exercise.

The amount of information that labs will be reporting to CMS – and the number of labs reporting – dwarfs the amount that had to be reported to the Medi-Cal program. Just one laboratory may have payor agreements with over one thousand private payors, as that term is defined in the statute, with separate rates for each of the more than one thousand test codes on the CLFS, and different rates for each of the private payor's plan offerings. Layered on to each of these separate data points is the volume for each test code for each private payor's own plan offerings. Each laboratory that is considered an "applicable laboratory" is to report all of this data to CMS. CMS

must be prepared to receive an overwhelming amount of data and to provide laboratories with flexibility about how they report such data.

ACLA believes there may be alternative reporting methods that would reduce the burden on both labs and CMS, and still result in Medicare reimbursement rates that reflect true market rates for laboratory services. We are exploring alternatives with our membership and other laboratory stakeholders, and encourage the agency to research and consider proposing alternatives as well.

C. Data Collection Period and Reporting Deadline

1. The Law

For most clinical laboratory tests the new market-based rates are to take effect on January 1, 2017.[8] CMS is to issue a final rule implementing the data collection provisions of Section 216 of PAMA no later than June 30, 2015, and reporting is to begin no sooner than January 1, 2016.[9] (CMS may issue a final rule earlier than June 30, 2015, and it may select a data reporting deadline that is months after January 1, 2016.) The law does not specify the length of the data collection period nor its timing; it simply defines the data collection period as "a period of time, such as a previous 12 month period, specified by the Secretary."[10]

2. Length and Timing of the Data Collection Period

ACLA believes that the data collection period that CMS establishes should be long enough to allow the agency to collect enough data to develop accurate market-based payment rates, but it should not require laboratories to report more data than is necessary. For some commonly performed high-volume tests, such as a complete blood count, one calendar quarter worth of data

[8] Social Security Act § 1834A(b)(1)(A) (42 U.S.C. § 1395m-1(b)(1)(A)).
[9] Social Security Act §§ 1834A(a)(1), 1834A(a)(12) (42 U.S.C. §§ 1395m-1(a)(1), 1395m-1(a)(12)).
[10] Social Security Act § 1834A(a)(4) (42 U.S.C. § 1395m-1(a)(4)).

should be sufficient for CMS to calculate a weighted median that reflects private payor rates in the market. For other tests that are not as common, that are performed by just a handful of laboratories, or that are not covered and paid for by as many private payors, the data collection period may have to be longer for CMS to assemble enough data points to reflect the private payor market. Generally, we believe that six months' worth of data will be sufficient for CMS to develop accurate rates.

The timing of the data collection period also is important. The data that applicable laboratories are to report is to include information on "each laboratory test that the laboratory furnishes during the [data collection] period."[11] Of course, some tests furnished during the data collection period may not be adjudicated for months after the data collection period's close. This lag in payment is particularly pronounced for an out-of-network laboratory that does not have a contract with a given payor to whom it has submitted a claim. A claim must be adjudicated in order for a laboratory to report its payment rate; otherwise, the laboratory cannot know what the payment rate is. Therefore, we suggest that there be some time between the end of the data collection period and the date by which payment rates must be reported in order to account for this adjudication lag and to allow laboratories to collect and assemble all information. Six months appears to be a reasonable amount of time to ensure that most claims are adjudicated. ACLA and its members are available to consult with CMS further about the length of the data collection period and its timing.

D. Other Reporting Issues

ACLA suggests that CMS establish an electronic reporting mechanism, such as an internet-based portal, for laboratories to use to report their private payor rates. CMS also should provide

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

opportunities for laboratories to test their own rate reporting capabilities prior to the actual reporting deadline, which also would allow the agency to evaluate its own readiness to accept the information electronically. Whatever reporting mechanism the agency develops, it must be workable for many different kinds of laboratories with different information technology capabilities and resources, and it must be user-friendly and secure. We hope that CMS will 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.

III. RATE DEVELOPMENT

A. Development of Weighted Median

For a clinical laboratory test furnished on or after January 1, 2017 (other than 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 is to be derived by "arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory."[12] An ADLT will be paid initially at the "actual list charge," and after three calendar quarters, Medicare will pay a weighted median of the private payor rates reported during the second quarter.[13]

As important as how CMS collects private payor data from applicable laboratories is what the agency does with the data once it has been submitted. It is critical to ACLA's members that the Medicare payment rates are developed accurately and transparently to ensure appropriate Medicare payments and because many other payors base their rates on Medicare rates. Congress did not give CMS much direction about how to determine weighted medians, but transparency is

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

of utmost importance to bolstering the credibility of the process. We ask that the agency provide the public with a detailed explanation of its proposed method for developing weighted medians and how it will array private payor data for each test code.

The rate-setting method for ADLTs will apply to fewer tests, yet it is important the CMS carefully consider how it implements this provision of the law. The initial "three quarters" during which the "actual list charge" applies should begin once a Medicare Administrative Contractor ("MAC") determines that an ADLT is covered by Medicare. The weighted median should be developed based on as much data as possible. There may be fewer private payors covering and paying for a new ADLT early in its development, so CMS should consider a data collection period that includes payment by private payors even before the date of Medicare coverage.

B. Data Review

While we hope that CMS's rate-setting method is reliable and accurate, it is reasonable to expect that from time to time, some calculations may not be accurate. CMS should permit stakeholders to review preliminary payment rates prior to their effective dates and to request that CMS review potentially inaccurate rates. One way to facilitate this is publishing preliminary payment rates at least three months prior to their effective date.

C. 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.[14] ACLA seeks assurance from CMS that disclosures

[14] "Notwithstanding any other provision of law, information disclosed by a laboratory under this subsection is confidential and shall not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identify of a specific payor or laboratory, or prices charged or payments made to any laboratory, except (A) as the Secretary determines to be necessary to carry out this section; (B) to permit the Comptroller General to review the information provided; (C) to permit the Congressional Budget Office to review the information provided; and (D) to permit the Medicare Payment Advisory Commission to review the information provided." Social Security Act § 1834A(a)(10) (42 U.S.C. § 1395m-1(a)(10)).

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. 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.

IV. OTHER ISSUES

A. Expert Advisory Panel

The law calls for the establishment of an "expert outside advisory panel" no later than July 1, 2015 to provide input to CMS on payment rates, factors to consider for coverage and payment processes, and any other issues raised under the CLFS reform law. 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.[15] ACLA believes 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; and clinicians who use clinical laboratory test results. 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.

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

B. Local Coverage Determinations

ACLA is encouraged that the law ensures that Local Coverage Determinations 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.

V. CONCLUSION

We appreciate the opportunity to share our comments and recommendations with you, and we look forward to continuing to work with CMS in the coming years on implementing Section 216 of PAMA.