August 27, 2014

American Clinical Laboratory Association

Administrator Marilyn Tavenner
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models, and Other Revisions to Part B for CY 2015; Proposed Rule (CMS-1612-P)

Dear Ms. Tavenner,

The American Clinical Laboratory Association ("ACLA") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS's" or "the agency's") proposed rule on revisions to the Physician Fee Schedule, Clinical Laboratory Fee Schedule, and Part B payment for calendar year ("CY") 2015.[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies have a direct stake in ensuring that prices for laboratory testing services are developed openly and rationally and that the pricing levels represent reasonable compensation for developing and providing the services.

I. Summary of ACLA's Comments

Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing: Changes to the policies that govern the way LCDs are issued and challenged should be designed to result in greater clarity for laboratories, beneficiaries, and Medicare Administrative Contractors ("MACs") alike. Any changes should lead to an adequate opportunity to provide meaningful input, as well as provide transparency about coverage decisions. CMS should amend its proposal before finalizing it to clarify that non-coverage policies must be included in LCDs, rather than in articles, and to adjust certain proposals for public input.

Process for Valuing New, Revised, and Potentially Misvalued Codes: ACLA supports CMS's proposal to change the process for valuing new, revised, and potentially misvalued codes because it will allow for more meaningful public input before changes are made to codes and their values.

Potentially Misvalued Services under the PFS: We disagree with CMS's basis for suggesting that CPT code 88185 (flow cytometry, each additional marker) potentially is a misvalued service, simply because it is a code commonly used by pathologists. If CMS proceeds with revaluing this code, it should do so in the CY 2016 Physician Fee Schedule rulemaking

[1] 79 Fed. Reg. 40318 (July 11, 2014) ("Proposed Rule").

cycle, using the proposed process for valuing potentially misvalued codes, rather than including a new value in the CY 2015 Physician Fee Schedule final rule. We also are discouraged by CMS's inclusion of G0416 (prostate biopsy) among potentially misvalued codes. The agency's changing approach to prostate biopsy codes recently has been confounding, and we are concerned that there is not a clear understanding of the procedures that the codes represent, making a determination about the appropriateness of their valuation difficult at best.

Valuing New, Revised, and Potentially Misvalued Codes: As ACLA has expressed to CMS in the past, we are concerned about the agency's approach to immunohistochemistry stains and FISH probes and the lack of clarity about how these procedures are used in the laboratory setting. We urge CMS to revise its policies in the manner that ACLA and other organizations have suggested to the agency in the past.

Using OPPS and ASC Rates in Developing PE RVUs: We are concerned about the use of data derived from the Outpatient Prospective Payment System ("OPPS") and from ambulatory surgery center ("ASC") rate-setting for use in developing professional expense relative value units ("PE RVUs") for the purpose of setting Physician Fee Schedule ("PFS") rates. We have shared our concerns in the past with CMS that the OPPS and PFS are entirely different payment systems with different designs and different inputs, and direct comparisons of resources and costs in the two systems is inappropriate.

Adjustments to the CLFS Based on Technological Changes: We support the agency's decision to retract its proposal from the CY 2014 rulemaking cycle to adjust rates on the CLFS based on "technological changes."

PQRS pathology measures: ACLA supports the inclusion of PQRS measures related to lung cancer reporting and melanoma reporting.

II. Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing

CMS has proposed several changes to the LCD process as it exists today.[2] Any person, organization, or the MAC could initiate an LCD for clinical diagnostic testing. The MAC would publish a draft LCD in the Medicare Coverage Database, and the minimum public comment period would be reduced to 30 days from 45 days. CMS says that it "would expect the draft LCDs to outline the criteria the MAC would use when determining whether a specific clinical diagnostic laboratory test or group of tests is covered or non-covered." The MAC would have the discretion to take an LCD to the Carrier Advisory Committee ("CAC") but it would not be required to; if the CAC were consulted, the public comment period would be extended to accommodate this additional step. Additionally, there would be no requirement for a MAC to hold a public stakeholder meeting on a draft LCD. The MAC would be required to respond to all public comments in writing and to post its responses on a public website. The MAC would publish the final LCD in the Medicare Coverage Database no later than 45 days after the close of

[2] 79 Fed. Reg. 40378.

the public comment period, and the final LCD would be effective upon publication. The reconsideration process would not change, nor would the current challenge process.[3]

ACLA supports changes to the way LCDs are issued for clinical laboratory tests if those changes improve the clarity of coverage policies, foster transparency in the process, implement additional safeguards for stakeholders, and provide clear direction to the MACs about the proper role and contents of an LCD. We have some concerns as to whether the proposed changes will achieve these goals.

A. The Use of Articles to Announce Coverage and Non-Coverage Policies

It is important to recognize the context in which CMS is proposing changes to the LCD process for clinical laboratory tests. In the past, ACLA and other organizations have expressed concerns about the way that coverage decisions have been made in the Molecular Diagnostic Services program ("MolDx") and the need for adequate transparency and opportunity to comment on non-coverage decisions. One issue that has been challenging for laboratories is the use of articles to announce non-coverage decisions. Articles are not subject to the same requirements as LCDs; therefore, when a contractor issues an article that effectively denies coverage for a test, affected laboratories do not have the same ability to comment or submit information on the test at issue. In some cases, laboratories first learn about non-coverage of a test when an article is posted on the MolDx website. In addition, sometimes the contractor simply determines that a test is "statutorily excluded," which technically is not a coverage decision and therefore does not necessarily require an LCD. While one contractor has provided stakeholders with some ability to seek reconsideration of such decisions, it is ACLA's view that many of these "statutorily excluded" determinations are actually decisions that a test lacks adequate evidence for coverage, and therefore they should be considered coverage decisions, with the commensurate procedural requirements.

In the recently-enacted Protecting Access to Medicare Act of 2014 ("PAMA"), Congress also acknowledged concerns about contractors' misuse of the LCD process. Section 216 of PAMA[4] added section 1834A(g) to the Social Security Act, which requires that, for LCDs issued on or after January 1, 2015, "a Medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination (as defined in section 1869(f)(2)(B)), including the appeals and review process for local coverage determinations under part 426 of title 42, Code of Federal Regulations (or successor regulations)." Congress clearly included this provision in PAMA in response to the concerns noted above regarding the use of "articles" and the overuse of the "statutorily excluded" rationale for non-coverage.

Given the attention that Congress has paid to this issue, it is somewhat surprising that CMS would propose changes to the LCD process that *reduce* the procedural protections that currently apply to clinical laboratory LCDs. In passing the provisions of PAMA section 216 dealing with LCDs, it is clear that Congress intended for CMS to ensure that the *current*

[3] *See* 42 C.F.R. Part 426, Subpart D.
[4] Pub. L. 113-93.

requirements for LCDs be applied to all LCDs going forward. Therefore, if CMS is going to change the LCD process at this time for clinical laboratory tests, it should do so in a way that is consistent with Congress' goals in enacting the LCD provision in PAMA section 216. Most importantly, in its discussion of proposed revisions of the LCD process, CMS does not state whether or not articles may be used in lieu of LCDs to announce non-coverage of clinical diagnostic laboratory tests. CMS addresses articles issued by Palmetto GBA in the context of the MolDx program, stating that the articles address "various aspects of the LCD implementation process, including coverage, coding guidelines, billing, and medical review procedures" and "there is much information that is not contained in the body of an LCD that is necessary for consistent and predictable claims processing and payment." We do not believe that non-coverage decisions should be announced in articles, and we urge CMS to make it clear in the final rule that they may not be used in this way.

It is not sufficient for CMS to say that it "would expect" a draft LCD to outline the criteria the MAC would use when determining whether a specific clinical diagnostic laboratory test or group of tests is non-covered. By definition, an LCD is a determination of whether an item or service is covered by a Medicare contractor, and such a determination should not be announced initially in an article.[5] CMS should provide clear information to stakeholders and the MACs about the inclusion of coverage decisions in LCDs, what information may be included in articles, and when they may be used. At the very least, CMS should make clear that a non-coverage decision must be included in an LCD so that stakeholders have adequate opportunity to comment and so that the review and appeals processes will apply. In addition, it also must clearly define when it is appropriate for a contractor to deny payment for a test because it is "statutorily excluded." CMS should mandate that "statutorily excluded" decisions are appropriate only when a test is used for "screening purposes" in the absence of other signs and symptoms and that it is not an appropriate statement when the contractor simply believes that the test lacks adequate evidence of medical necessity. CMS should identify the specific circumstances under which coverage articles may be used.

B. Revised Timeframes

Comment period: We are concerned about shortening the public comment period from the current 45-day period on draft LCDs to 30 days. Again, we find such a change in the procedural requirements especially surprising in light of Congress's mandate in PAMA section 216 that contractors must follow the *current* statutory requirements with regard to LCDs, which includes a minimum 45-day comment period.

Our experience is that in many cases, the current allotment of 45 days is insufficient, especially for LCDs that address many items or services together and that contain complex coverage conditions. Each of the MACs posts draft LCDs in a different place and communicates with stakeholders in a different manner, and it is difficult for laboratories and other stakeholders to keep abreast of all of the various proposals and develop comments timely, even with 45 days to comment. The proliferation of policies for molecular diagnostics from many different MACs

[5] 42 U.S.C. § 1395ff(f)(2)(B).

requires laboratories to respond to multiple draft LCDs in multiple jurisdictions simultaneously. For this and other reasons, 30 days is an insufficient time in which to comment effectively.

CMS acknowledges the difficulty that some stakeholders have in commenting on draft LCDs timely, and we appreciate the inclusion of a deadline extension mechanism that a MAC could use.[6] However, rather than an *ad hoc* extension at the discretion of each MAC, to maintain the quality of stakeholder input on draft LCDs and to receive comments from a broad cross-section of affected entities, we recommend that CMS should maintain the current comment period of 45 days.

Effective date: CMS proposes that a MAC would publish stakeholders' comments and its responses to each within 45 days after the close of the comment period, along with the final LCD, which would become effective immediately upon publication. Making the LCD effective immediately upon publication is a "double edged sword." As CMS states, having an immediate effective date "is an efficient mechanism to make tests available to beneficiaries more quickly." This is true for LCDs that announce affirmative coverage policies. However, when a MAC announces in a final LCD that it no longer will cover a clinical diagnostic test, or the conditions under which a test will be covered are extremely limited, it can be difficult for laboratories offering the test to respond to such an abrupt policy change. Therefore, we believe that coverage denials or changes in coverage conditions should continue to be effective 45 days after the final decision is made. Again, we note this is exactly the requirement that currently exists in the rules, which applies to other non-laboratory LCDs, and which was the requirement when Congress passed PAMA section 216.[7]

C. Use of the Carrier Advisory Committee and Public Stakeholder Meetings

CMS believes that the CAC can be used more effectively if a MAC is permitted to decide which LCDs are presented to the CAC. We agree that it probably is not necessary for each draft LCD to be submitted to a CAC, and the quality of the discussion at CAC meetings sometimes suffers because of the large number of LCDs being considered at one time. On the other hand, as CMS has pointed out, they provide valuable practical information to MACs about how services are delivered in a particular community. While it may be difficult to establish a hard-and-fast rule about when a CAC should be consulted, we ask that CMS provide MACs with more guidance about the circumstances under which the CAC should be involved. At a minimum, CACs should be consulted on non-coverage LCDs and on LCDs that restrict coverage. CACs also should be consulted on LCDs that are controversial, LCDs about which highly-invested stakeholders hold markedly different viewpoints, and LCDs that address a broad class of clinical laboratory tests, rather than one specific test. CMS should require MACs to consult the CAC in these and other similar circumstances.

The same principles should apply to public meetings on LCDs. A public meeting can be a valuable safeguard that ensures that stakeholders' concerns are heard and addressed. CMS

[6] 79 Fed. Reg. 40380 ("We note that in the event that stakeholders and/or members of the public are not able to submit comments within the 30 calendar day window, the MAC would have discretion to extend the comment period.").
[7] See Medicare Program Integrity Manual, Ch. 13, § 13.7.4.3.

should direct the MACs to hold public meetings on non-coverage LCDs, LCDs that restrict coverage, LCDs that are controversial, LCDs about which highly-invested stakeholders hold markedly different viewpoints, and LCDs that address a broad class of clinical laboratory tests, rather than one specific test.

D. LCDs to Which the Revised Policy Would Not Apply

As proposed, CMS's LCD policy for clinical laboratory tests would not apply to LCDs "being revised to liberalize an existing LCD; being issued for a compelling reason; making a non-substantive correction; providing a clarification; making a non-discretionary coverage or diagnosis coding update; making a discretionary diagnosis coding update that does not restrict; or revising to effectuate an Administrative Law Judge's decision on a Benefits Improvement Protection Act 522 challenge." CMS should make clear to stakeholders and to the MACs what is meant by an LCD "being issued for a compelling reason." Issuing an LCD for a compelling reason is not mutually exclusive with receiving comments on it, and we want to ensure that such a justification is not abused. It also is not clear whether any of these types of LCDs would be subject to reconsideration or challenge. CMS should provide clarity on this point when finalizing any new clinical laboratory test-specific LCD process.

III. Process for Valuing New, Revised, and Potentially Misvalued Codes

CMS proposes to revise the current process for valuing new, revised, and potentially misvalued codes such that all such codes will be included in a proposed rule. For those codes for which CMS has a complete recommendation from the American Medical Association's Relative Value Scale Update Committee ("RUC") by January 15 of a year, CMS would review the RUC's recommendation and propose new work and malpractice relative value units ("RVUs") and direct Practice Expense ("PE") inputs in the PFS rule that year. For those codes for which CMS does not receive a complete RUC recommendation by January 15 of a year, CMS would wait until the following year's PFS proposed rule to propose new RVUs and PE inputs. If such a code's CPT descriptor has not changed, CMS would maintain the valuation until it receives public input through notice-and-comment rulemaking. If such a code's CPT descriptor did change, CMS would create a G-code with the same CPT descriptor (if possible) and include the G-code in the PFS final rule that year. For an entirely new code about which the agency does not receive a timely RUC recommendation, CMS would establish an interim value and contractor-price the code in the initial year. The agency also included in the Proposed Rule two alternatives that it considered but rejected: a hybrid approach that would include some codes in the PFS proposed rule and some codes in the PFS final rule (depending on when CMS received information from the RUC), or maintaining the current process while increasing transparency regarding the agency's thinking on code value development.

ACLA favors changing the current system for valuing new, revised, and potentially misvalued codes, rather than the alternative of maintaining the current process, even with efforts aimed at increased transparency. We do not believe that CMS should implement this system gradually; rather, it should be implemented as soon as possible in the CY 2016 rulemaking cycle. The current system does not provide stakeholders ample opportunity to comment on new values before they take effect, which generally is about two months after inclusion in a final rule

(sometimes the period is even shorter). The proposed system would provide stakeholders with a meaningful opportunity to comment on proposed values for all new, revised, and potentially misvalued codes.

The proposed system would give stakeholders an opportunity to comment on G-codes that CMS creates for expiring or revised CPT codes. When CMS issues G-codes to be used in lieu of expiring or revised CPT codes, it should maintain current values for the codes, rather than issuing G-codes with interim values for those codes. CMS rightly notes the administrative burden that G-codes pose, and we do not favor the increased use of G-codes. However, the temporary use of G-codes for revised and expiring CPT codes, along with a continuation of the codes' values until stakeholders can comment on new proposed values, is preferable to the current system and preferable to interim G-codes with interim values.

We hope that CMS will work with the RUC to amend the RUC's review schedule so that CMS receives as many complete recommendations each year by January 15. This will reduce the need for creation of G-codes when CPT code descriptors change, interim contractor pricing, and lengthy delays in consideration of proposed values. Alternatively, CMS could push back the deadline for receiving complete recommendations from the RUC to February 15, which could accommodate recommendations that come out of the RUC's October and January meetings.

IV. Potentially Misvalued Services under the PFS

A. Codes Based on Review of High Expenditure Services Across Specialties with Medicare Allowed Charges of $10 Million or More

In section 220(c) of PAMA, Congress gave CMS the authority to review as potentially misvalued those codes that meet certain criteria.[8] One code CMS is proposing to review pursuant to that authority is CPT code 88185 (flow cytometry, each additional marker). CMS says it was one of the more than 60 codes that "account for the majority of spending under the physician fee schedule."[9] CMS did not choose simply to review the codes that comprise the majority of spending under the PFS; rather, it prioritized codes by identifying the top 20 codes by specialty in terms of allowed charges. Presumably, CPT code 88185 is one of the top codes used by pathologists.

The statute includes several criteria CMS could use to select potentially misvalued codes for review, but the "top 20 codes by specialty in terms of allowed charges" is not among them, and CMS should not use it. CMS has not said what it sees as the correlation between a code used often by a specialty and the possibility that it is misvalued; the agency says only that the codes "may be important to a segment of Medicare practitioners."[10] Regardless, it is not unreasonable to expect that CPT 88185 would be among the top codes, by charges, used by pathologists, given the high incidence of cancer in the Medicare-aged population. Further, this is an add-on code, used in conjunction with a primary code (CPT code 88184, flow cytometry, first marker), and multiple markers typically are performed in flow cytometry. That means that for

[8] 42 U.S.C. § 1395w-4(c)(2)(K)(ii).
[9] 42 U.S.C. § 1395w-4(c)(2)(K)(ii)(VII).
[10] 79 Fed. Reg. 40337.

each test using flow cytometry, CPT code 88185 would be used multiple times (in contrast to CPT code 88184, which would be used once). It is not unreasonable for CPT code 88185 to be one of the top codes used by pathologists, nor does its prevalence suggest that it is misvalued.

Rather than select the top codes relevant to a specialty, CMS should heed the limits of the statute and, if appropriate, review codes that account for a majority of spending under the physician fee schedule, based on allowed charges for those codes. Therefore, CMS should withdraw its proposal to review CPT code 88185 as a potentially misvalued code.

However, if CMS intends to adopt a new valuation for CPT code 88185 despite its inappropriate selection as a potentially misvalued code, it should do so using the process it is proposing for valuation of new, revised, and potentially misvalued codes. The new valuation should be published for comment in the 2016 Physician Fee Schedule proposed rule, rather than in the 2015 Physician Fee Schedule final rule.

B. Prostate Biopsy Codes—HCPCS Codes G0416, G0417, G0418, and G0419

CMS proposes to use just one HCPCS code – G0416 – to describe all prostate needle biopsy procedures, regardless of the number of specimens, and regardless of the methodology (standard prostate biopsy versus saturation prostate biopsy). It proposes to delete G0417, G0418, and G0419. CMS also is proposing G0416 as a potentially misvalued code and seeks input on the appropriate work RVUs, work time, and direct PE inputs.

CMS continues to be completely misguided in its approach to these codes. As we have discussed with the agency repeatedly, HCPCS codes G0416 through G0419 originally were developed to apply to a relatively rare procedure, prostate needle saturation biopsies, which are done under general anesthetic and involve biopsy of the entire prostate in order to determine if previously diagnosed prostate cancer is spreading. However, last year, CMS decided to apply these codes to a standard biopsy, which is a far more common procedure, done under local anesthetic, and which involves taking fewer biopsies to determine if cancer could be present in the first instance. These latter types of procedures always previously were billed under CPT 88305. It is inappropriate for CMS to treat these two vastly different procedures as the same, and to include them under the same HCPCS code.

Finally, we find it unreasonable that CMS would consider this procedure a misvalued code. CMS notes that most prostate biopsies (which CMS itself says are for standard biopsies and not saturation biopsies) are billed for 10 to 12 biopsies. The current rate for the G-code is $651.26, or about 54.25 per specimen, for a standard 12-biopsy specimen. That reimbursement already is almost 30 percent below the level that ACLA believes is appropriate, which would be 12 units of 88305, or approximately $847.00. CMS has failed to explain why it believes that a significant reduction in HCPCS code G0416 may be appropriate when it bundles the codes together. Moreover, CPT 88305 itself was significantly reduced several years ago, on the basis that it was misvalued; therefore, to reduce the payment even further below the current levels seems unwarranted.

V. Valuing New, Revised, and Potentially Misvalued Codes

In the CY 2014 PFS Rule issued in December, 2013, CMS created a new HCPCS code for immunohistochemistry ("IHC") stains and made significant changes in the payment levels as well. In our comments last year, we addressed our concerns with these changes and subsequently met with CMS to discuss our concerns. CMS should adopt the AMA CPT codes for IHC stains, which account for the resources and work involved in staining and analyzing separately-identifiable antibodies on each slide, or adopt G-codes that closely track the "per-slide" descriptors of the CPT codes for the first separately-identifiable antibody and each additional separately-identifiable antibody. This approach also would simplify laboratories' coding and billing practices, as most commercial payors have adopted the AMA codes. As an alternative, CMS should work with the laboratory community to develop G-codes that are fairer and more closely account for the actual cost and time involved in providing the service.

At the same time, through the NCCI process, CMS implemented similar changes to FISH testing, which also are inappropriate given the way the service is delivered. (The FISH policy allows reimbursement for only a single FISH probe, when the test itself always requires that several probes be used.) It is reasonable that when a laboratory must do twice the analysis and interpretation of additional probes, it should be compensated for the additional work. Our members' experiences in the time since these policies were issued have made clear the problems created by these misguided policies. We urge CMS to reconsider these policies and to revise them in the manner suggested by ACLA and other industry groups.

VI. Using OPPS and ASC Rates in Developing PE RVUs

A. Limiting Non-Facility PE RVUs Based on Facility Rates

CMS has decided not to implement its proposal from the CY 2014 rulemaking cycle to limit the non-facility PE RVUs for individual codes so that the total non-facility PFS payment amount would not exceed the total combined amount that Medicare would pay for the code in the facility setting.[11] ACLA supports CMS's decision not to implement this policy. As we stated in our comments on the CY 2014 PFS proposed rule, that proposed policy was built upon the faulty assumption that facility cost reports yield more accurate data about the actual cost of providing a service and that the cost to perform a service in a physician's office always must be lower. The OPPS and PFS systems are hardly comparable, being derived through entirely different methodologies and for different purposes, and individual codes on the PFS cannot and should not be compared to Ambulatory Payment Classification ("APC") rates in the facility context. Not only does the proposal lack a sound policy basis, but it would discourage innovation and continued offering of certain assays by slashing reimbursement for tests that are vital to the treatment of Medicare beneficiaries with cancer and other serious diseases.

[11] *See* 78 Fed. Reg. 43296 (Jul. 19, 2013).

B. Uses of Medicare Hospital Outpatient Cost Data in Developing PFS PE RVUs

At the same time that CMS states that it has been "persuaded that the comparison of OPPS (or ASC) payment amounts to PFS payments amounts for particular procedures is not the most appropriate or effective approach to ensuring that the PFS payment rates are based on accurate cost assumptions," it seeks comment on possible uses of Medicare cost data in potential revisions of the PFS PE methodology.[12] The agency has invited stakeholders to consider a wide range of options for gathering and using the data, including using it to validate or set resource assumptions for only a subset of PFS services, as a base amount to be adjusted by code or specialty-level, or other uses. It is difficult for ACLA to comment definitively on CMS's proposal, as the agency has not said how it might use such data to supplement other resource information developed specifically for the PFS. Also, CMS has not said for what "subset of PFS services" the agency would consider using the data to validate resource assumptions – or why it would be appropriate to do so for only some services paid for under the PFS, but not all.

As we have made clear to CMS in the past, the PFS and the OPPS are two entirely different payment systems. The payment levels are different because they were designed to be different. They are based on completely different approaches to health care reimbursement. While the PFS pays for services on a code-by-code basis, the OPPS groups similar services together into bundled payments. This is significant because the bundling approach may underpay for certain services but it will overpay for others. This is not a problem under the OPPS system, because the theory behind the approach is that within a single hospital, the payment amounts will average out. Additionally, a hospital outpatient "cost" is not the same as the cost of performing a procedure, and the concept does not translate to a fee-for-service system such as the PFS.[13]

If CMS determined at some point in the future to use Medicare facility cost data to adjust PFS rates, ACLA and many other stakeholders would need assurance from the agency that it would not use such data to make unidirectional adjustments downward. We were concerned last year that CMS's proposal to limit non-facility PE RVUs so that a total payment under the PFS did not exceed the payment in a facility setting was one-sided; that is, CMS would have reduced PFS rates that exceeded OPPS rates, but it would not have raised PFS rates to match OPPS rates for the same or similar service. If CMS truly believes that the "routinely updated, auditable resource cost information" derived in the facility setting yields a more accurate picture of the relative costs of providing services, it should be willing to adjust rates to equalize them across settings.

---

[12] 79 Fed. Reg. 40333.

[13] CMS itself has said, "We note that, in general, the median cost derived from this process may not represent the actual acquisition costs of the services being furnished, nor will they ever represent acquisition costs. They are estimated relative costs that are converted to relative weights, scaled for budget neutrality, and then multiplied by a conversion factor to result in payments that, as we have previously discussed, were designed in such a manner they are not expected to pay the full costs of the services." 70 Fed. Reg. 68516, 68621 (Nov. 10, 2005).

VII. Adjustments to the CLFS Based on Technological Changes

We agree with CMS's proposal to remove § 414.511 from title 42 of the Code of Federal Regulations, since Congress rescinded CMS's authority to adjust prices on the Clinical Laboratory Fee Schedule based on technological changes when it passed PAMA earlier this year.

VIII. PQRS Pathology Measures

ACLA supports the inclusion of the three new pathology-related measures in the Physician Quality Reporting System ("PQRS"). These are: Lung Cancer Reporting (Biopsy/Cytology Specimens); Lung Cancer Reporting (Resection Specimens); and Melanoma Reporting. We agree with CMS that it should exercise its authority to make an exception to the requirement that it select measures only if they have been endorsed by the National Quality Forum, because there are few PQRS measures applicable to the pathology specialty.

Thank you for your attention to ACLA's ideas and concerns.

Sincerely,

Alan Mertz, President
American Clinical Laboratory Association