September 24, 2013

American Clinical Laboratory Association

Glenn M. Hackbarth, J.D., Chairman
Medicare Payment Advisory Commission
425 Eye Street, NW, Suite 701
Washington, DC 20001

Dear Chairman Hackbarth:

The American Clinical Laboratory Association is taking this opportunity to share our views on the recent comments submitted to the Centers for Medicare and Medicaid Services ("CMS") by the Medicare Payment Advisory Commission ("MedPAC" or "the Commission") with regard to the 2014 Medicare Physician Fee Schedule ("PFS") proposed rule ("the Proposed Rule").[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional and national laboratories. ACLA members would be affected directly by many of the policies that CMS included in the proposed rule. ACLA respectfully disagrees with some of MedPAC's comments. We would welcome the opportunity to discuss these issues further with you and the MedPAC staff.

In its comments, MedPAC discussed three issues of significance to laboratories: (1) using Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgery Center ("ASC") rates in developing professional expense relative value units ("PE RVUs") under the PFS ("the OPPS Cap"); (2) the multiple procedure payment reduction ("MPPR") policy; and (3) revisions to the Clinical Lab Fee Schedule ("CLFS") to reflect technological changes. Our views on the Commission's comments are set out below.

I. Using OPPS and ASC Rates in Developing PE RVUs

A. CMS's Proposal

In the Proposed Rule, CMS proposes to change the practice expense rate setting methodology beginning in 2014. CMS states it would compare the PFS payment rate for a service furnished in the non-facility setting to the total Medicare payment for the same service when furnished in a hospital outpatient setting. CMS proposes to limit the non-facility PE RVUs so that the total payment would not exceed the payment made in the facility setting. In performing this calculation, CMS applies the 2013 conversion factor to the unadjusted RVUs. CMS also proposed to exclude services for which five percent or less of the total number of services are furnished in the OPPS setting relative to the total number of PFS/OPPS allowed services.

[1] Letter of Glenn M. Hackbarth, JD, Chair, to Marilyn Tavenner, CMS Administrator (Aug. 30, 2013).

B. MedPAC's Comments

In its comments on the OPPS Cap proposal, the Commission discusses its own review of the differences in payment between various patient settings, including recent reports in which it recommended that payment for evaluation and management ("E&M") hospital visits be reduced to the amount paid when the same visit is provided in a free-standing office, which it says is the lower cost setting. In its June 2013 report, MedPAC identified 66 groups of services provided in hospital outpatient departments and offices that met the Commission's principles for aligning payment rates across settings. It noted that aligning the payment rates across settings for most of these services reduced the OPPS payment rate to that which is paid in the non-facility setting. However, in some instances it also found the OPPS rate would increase where the total payment rate for a service was higher in the non-facility setting.[2]

In reviewing the OPPS Cap contained in the Proposed Rule, MedPAC concludes that where the payment for a service in the non-facility setting exceeds the total rate when it is furnished in the facility setting, then there may be reason to believe that the non-facility practice expense is overvalued. It proposes that CMS and the American Medical Association Relative Value Scale Update Commission ("the RUC") should expedite a review of practice expense RVUs to ensure they are valued appropriately. While this practice is ongoing, however, MedPAC recommends that CMS reduce the RVUs for those codes so that the non-facility rate equals the hospital outpatient rate. These new interim RVUs would be in effect while the RUC and CMS perform their review.

C. ACLA's Views

There are 38 Common Procedural Terminology ("CPT") codes for a variety of anatomic pathology services that would be affected by the OPPS Cap proposal. As shown in the chart included in our comments, a copy of which is attached hereto, the reduction resulting from the OPPS Cap would be anywhere from approximately 30 percent to over 80 percent for these codes. Many of the proposed rates are not even sufficient to cover the direct costs of providing the services. Put simply, most laboratories would find it extremely difficult to continue to provide the services to Medicare patients at these rates, and some laboratories almost certainly would stop offering the services entirely. Moreover, these reductions would have grave implications for patient care. Many of the services at issue, such as flow cytometry and *in situ* hybridization, are tests that are vital to the early diagnosis and treatment of cancer, including leukemia, lymphoma and breast cancer. It is unreasonable to expect that these services would continue to be available in the same manner as today if the reimbursement were to be cut in the draconian manner that CMS proposes.

First and most importantly, MedPAC does not offer any support for its statement that where the payment rate for a service in the non-facility setting exceeds the total rate when it is furnished in the outpatient department, it may indicate "that the practice expense RVUs for many

[2]MedPAC, "Chapter 2—Medicare Payment Differences Across Ambulatory Settings," *Report to Congress: Medicare and the Health Care Delivery System* (June 2013).

of these codes are overvalued." Indeed, as explained below, there are a number of reasons this statement is inaccurate. It is wholly inappropriate simply to assume that the outpatient rates are the proper benchmark to use in establishing payments made under both the OPPS and the PFS methodologies.

Indeed, in its past analyses, MedPAC has taken the opposite view. In its June 2013 report in which it examined Medicare payment differences across ambulatory settings for certain specified services, MedPAC looked to the PFS rates as establishing the appropriate level of payment. Where payments for the same service were higher in the hospital outpatient department setting than in a freestanding physicians' office, it proposed reducing the hospital payments. However, where payments in the hospital were lower than in the office setting—the very situation being considered by CMS—MedPAC proposed raising the hospital rates. CMS now proposes to do the exact opposite. If the payment in the hospital is lower, CMS proposes to cut the PFS payment, rather than increase the hospital payment, as MedPAC suggested. (CMS is not as even handed as MedPAC was, as CMS does not propose to increase any PFS payments that are lower than the hospital rate.)

In its June 2013 Report, MedPAC took the position that payments for Ambulatory Payment Classification ("APC") 0344, which includes many of the anatomic pathology services that would be subject to the OPPS Cap, actually were too low. Because the services were paid more under PFS than under the OPPS, the Commission suggested that CMS should increase the OPPS payment.[3] In that instance, MedPAC clearly did not believe the differential in payment was a sign that the PFS rate was too high; rather, it concluded just the opposite: that the payment under the OPPS rate was too low. In sum, MedPAC itself did not appear to believe that the differential in that case showed that the PFS codes were misvalued.[4]

Second, there are numerous reasons why the OPPS data should not be used to set payment levels for services delivered in non-facility settings. First, the PFS and OPPS are two entirely different payment systems. The payment levels are different because they were designed to be different. Just this year in the OPPS proposed rule, which was released on the very same day as the PFS Proposed Rule, CMS itself noted that OPPS is a prospective payment system and it is not intended to be a fee schedule in which separate payment is made for each coded line item. Further, OPPS payments represent the average payment for a bundle of services included in each APC. As a result, the payment may be low for some services in the bundle, but it will be high for others. From the hospital's standpoint, the payments average out because the hospital is supplying the whole mix of services in an APC. However, a laboratory (or other supplier) does not have the ability to offset the losses from inadequate payment on that service with the profits on others.

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[3] *Id*. at 40-41.

[4] We note also that CMS states that it would not apply the OPPS Cap to any service where five percent or less of the total number of services were furnished in the OPPS setting relative to the total number of allowed services. However, in most cases the services at issue are performed in the hospital outpatient department less than 30 percent of the time, and in many instances, the percentage is less than 20. We note this is far lower than the 50 percent cutoff that MedPAC used when it performed its own analysis.

CMS also has noted that cost reports are to be used in determining the relative costs of various procedures furnished within the hospital so that Medicare payments for those services can be distributed appropriately among the various APCs. However, it also stated 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 that they are not expected to pay the full costs of the services.[5]

Thus, it seems inappropriate now to claim that these APC payments provide a more accurate basis for payment, given that they are not designed to reflect the actual costs of providing the services.

Third, CMS's approach is based only on a comparison of the ***current*** payment amounts under the PFS and OPPS, as adjusted by CMS. CMS has based its proposal on a "snapshot in time" and would compare what the PFS rates otherwise would be in 2014 (using the 2013 conversion factor) to what the 2013 payment levels for the same service under the OPPS would be. It then would adjust the RVUs for the 2014 PFS to ensure that the PFS rate would not exceed the OPPS rate. However, this comparison skews results based on this year's data. Hospital rates and PFS rates change relative to each other each year as adjustments are made under both systems.

For example, APC 0343, one of the APCs that includes many of the pathology services at issue here, will increase from a payment of $38.10 in 2013 to $277.56 in 2014, an increase of over 600 percent. This far exceeds the 2013 PFS payment for this same service. If CMS waited just one year to undertake this exercise and compared the projected 2014 APC payment rates with the PFS payment levels, the hospital payments would far exceed the amounts paid under the PFS, eliminating the justification for imposing the OPPS Cap. In short, the fact that the PFS rate was higher than the hospital rate for one year appears to mean little if the rates change so dramatically from year to year. ACLA believes that this fluctuation in the relative rates undercuts the reasonableness of the OPPS Cap approach.

Finally, hospital cost reports do not accurately reflect the cost of providing anatomic pathology services. ACLA contracted with the Moran Company to conduct a review of the relevant inputs affecting CMS's proposal. The resulting report, entitled "The Effects of CMS's Proposed Cross Site Payment Caps on Reimbursement for Anatomic Pathology Services" ("the Moran Report"), is attached. As demonstrated in the Moran Report, there are significant concerns with the use of hospital cost reports as they apply to anatomic pathology services. The Moran Company conducted its own survey to determine how respondents' laboratory costs compare to those used by CMS under the OPPS system. That survey included some of the

[5] 70 Fed. Reg. 68516, 68621 (Nov. 10, 2005).

nation's largest laboratory companies, as well as numerous companies that specialize in anatomic pathology services. In virtually all cases, the average costs reported by the companies were significantly higher than those reflected in the OPPS rates. Moran concluded that it was likely that hospital cost accounting practices had underestimated the amount of direct and indirect costs associated with performing these procedures.

One reason why the OPPS data for anatomic pathology services may be inaccurate is that, until July 2012, many hospitals did not bill for anatomic pathology services. Under the "TC grandfather," independent laboratories were permitted to bill globally for the technical and professional components of anatomic pathology services if a hospital met certain requirements.[6] It is our understanding that in most cases, hospitals referred out these services to independent laboratories, which then billed Medicare for the services. Thus, given the fact that the grandfather was eliminated just recently in July 2012, it may be that many hospitals were unfamiliar with the costs of providing these services and did not report their costs accurately. Moreover, based on CMS's own data, even today these services are not performed in hospitals routinely.

D. Summary

In sum, ACLA believes that there is no basis for MedPAC's suggestion that the OPPS rate should be used as an interim payment amount while CMS and the RUC review practice expense RVUs. Indeed, as suggested above, many labs would be unable to furnish the services at all during the review period, given the significant cut that the OPPS payments would represent. We agree that CMS should work with the RUC to determine appropriate practice expense RVUs for codes that may be misvalued, authority that CMS already has under the Affordable Care Act. However, we do not agree that the OPPS rate should be used during the interim period, especially given the fact that it could take several years for CMS and the RUC to complete their review. Therefore, ACLA urges MedPAC to revise its recommendations and to eliminate the proposal to use the OPPS rate while the RUC and CMS perform their review.

II. Multiple Procedure Payment Reduction Policy

A. MedPAC's Proposal

As MedPAC notes, CMS has not proposed new MPPR policies for 2014; however, MedPAC encourages CMS to consider other opportunities to expand the MPPR. MedPAC states that some surgical pathology codes frequently are billed with more than one unit of service, which it suggests makes them candidates for possible application of the MPPR. MedPAC notes that claims for CPT 88305 (Level IV, surgical pathology) and CPT 88342 (immunohistochemistry) often include more than one unit of service. MedPAC also notes that a

[6] Under § 542 of the Benefit Improvement and Protection Act of 2000 ("BIPA"), an independent laboratory could bill and be paid for the technical component of a physician pathology service furnished to a "covered hospital." That provision was eliminated, effective June 30, 2012, by the Middle Class Tax Reform and Job Creation Act of 2012.

recent report by the Government Accountability Office ("GAO") found that Medicare's payment system provides a financial incentive to order a higher number of specimens per procedure.[7]

B. ACLA's Views

ACLA believes that pathology codes are not appropriate candidates for MPPR adjustments. Each pathology specimen must be prepared separately, preserved, and made into a slide. Each slide then must be examined by a pathologist to make a diagnosis. Thus, there is little opportunity for the types of efficiencies that usually trigger the MPPR policy. Moreover, CPT 88305 was the subject of a significant cut last year—over 50 percent in the technical component and over 30 percent on the global payment. Therefore, additional cuts resulting from the implementation of an MPPR adjustment would have severe deleterious effects on the ability of laboratories to provide these services, especially if the other cuts outlined above resulting from the OPPS Cap also are imposed.

Further, while MedPAC is correct that the GAO found that there sometimes is a financial incentive to order a higher number of procedures, the GAO reached this conclusion in the context of a study on the impact of physician self-referral. Thus, that incentive exists only where the ordering physician also bills for the service, a circumstance that is made possible by the existence of the In Office Ancillary Services ("IOAS") exception to the physician self-referral law. An independent laboratory that is not owned by self-referring physicians has no ability to affect the way that services are ordered or billed. It seems far more reasonable to close the IOAS loophole to eliminate this financial incentive than to implement an unfounded MPPR policy.

III. Clinical Lab Fee Schedule Adjustments

A. CMS's Proposal

In the Proposed Rule, CMS notes that the payment rates for many CLFS tests have not been adjusted to reflect technological changes. As a result, it proposes to develop a process to reconsider payment amounts to account for technology changes, including tools, machines, supplies, labor, skills, techniques and devices by which the tests are produced. Under its proposal, CMS will begin reviewing codes that have been on the CLFS the longest. Over time, CMS would review newer codes until it has reviewed all 1250 codes on the CLFS.

B. MedPAC's Comments

MedPAC states it supports the direction of CMS's proposal to determine whether technological changes have affected the appropriate price for tests paid for under the CLFS. MedPAC suggests two approaches that CMS could consider: (1) using Medicare Administrative Contractors ("MACs") to determine the impact of technology, or (2) examining rates paid by other payors such as the Federal Employees Health Benefits Program and the Veterans

[7] GAO, *Action Needed to Address Higher Use of Anatomic Pathology Services by Providers who Self-Refer"* (June 24, 2013).

Administration. It also suggests that CMS should focus first on codes with the highest volume of claims, rather than on those codes that have been on the fee schedule the longest.

C. ACLA's Views

ACLA agrees that it is possible that technological changes may have affected the costs of performing some laboratory tests, both positively and negatively. We look forward to working with CMS as it reviews the impact of technology on laboratory services. However, ACLA also has urged CMS to ensure that the review process is carried out transparently, consistently, and with the opportunity for meaningful involvement by stakeholders. ACLA also urged CMS to begin with a pilot program in which it reviews a limited number of test codes in order to obtain greater experience with the process.

ACLA is troubled by MedPAC's suggestion that CMS should use the MACs to assist it in this exercise, as it did with the recent gapfilling process. ACLA does not believe it would be appropriate to utilize the MACs, as MACs have no particular expertise on or insight into the impact of technological changes on laboratory testing. ACLA's recent experience with gapfilling raised numerous concerns. We found that many contractors did not communicate with laboratories about their processes or inputs and that CMS was unwilling or unable to facilitate that communication. Moreover, as MedPAC itself notes, "CMS does not explain what data it would use to examine technological changes and adjust payment rates for specific codes." We would be especially concerned about using MACs to make these determinations in the absence of any clear direction from CMS about appropriate bases for determinations that technological changes had affected pricing. ACLA believes that whatever process is used to determine the impact of technological changes, it should be far more transparent and open than the gapfilling process was, and should involve laboratories and other stakeholders far more.

We also have concerns with MedPAC's proposal to examine rates paid by other payors. The statute gives CMS the authority to adjust the CLFS based on changes to the consumer price index and technological changes, although this will be the first time that CMS has used its authority for technological changes. The statute does not grant CMS the authority to adjust rates based on amounts paid by other payors, as MedPAC suggests doing here. Further, there may be numerous reasons, such as exclusivity provisions or reduced documentation requirements, why other payors may have lower rates that Medicare. There certainly is no basis for determining that the rates paid by other payors reflect technological changes not considered by Medicare. Therefore, we do not believe this approach is appropriate.

Finally, MedPAC also suggests the possibility of competitive bidding as a way of adjusting the lab fee schedule. However, as MedPAC notes, the agency would have to seek legislative authority for such a program. While Congress proposed a demonstration project for competitive bidding for lab services in 2003, a federal court subsequently blocked the project and then Congress eliminated the authorization for the program. There were numerous concerns about the model proposed for that competitive bidding demonstration. Many labs would have been unable to participate because they did not offer the full menu of laboratory services required. Other labs that worked primarily in nursing homes or in underserved areas probably

would have gone out of business because they would have been unable to participate in the demonstration. As a result, Congress ultimately determined that the approach was not advisable. ACLA believes that Congress made the correct decision, and we do not believe competitive bidding is appropriate for the laboratory industry.[8]

In sum, we look forward to working with CMS on its review of technological changes that may have impacted prices on the CLFS, and we urge the agency to ensure the process is open and transparent. We do not, however, believe that the various options suggested by MedPAC are appropriate or likely to be productive.

We appreciate the opportunity to share our views on MedPAC's comments. We look forward to discussing these issues with you further.

Sincerely,

Alan Mertz

Alan Mertz
President

Cc: Jon Blum, CMS
Marc Hartstein, CMS
Ariel Winter, MedPAC

[8] ACLA agrees that starting with the oldest codes for the review envisioned in the Proposed Rule may not be the best approach. At a minimum, it may be reasonable to start by reviewing a limited number of tests and t hen spread the project over a larger number of years to allow it to gain more experience in the analysis.