March 27, 2013

American Clinical Laboratory Association

Mr. Marc Hartstein, Director
Hospital and Ambulatory Policy Group
Centers for Medicare and Medicaid Services
Mail Stop C4-01-26
7500 Security Boulevard
Baltimore, MD 21244

RE: Gapfilling for Molecular Pathology Tests

Dear Marc:

I am writing on behalf of ACLA to follow-up on our prior conversations regarding the gapfilling process for new molecular pathology codes, which CMS has mandated. As you know, in the past, ACLA has raised concerns about the fairness and transparency of the gapfilling process. Last month, in a letter to Center for Medicare Services Director Jon Blum, we again expressed our concerns about the way the gapfilling exercise was proceeding and the lack of transparency in the process. In our previous discussions, both you and Jon Blum urged us to give the process time to play out before taking any action. It now has been five months since the decision to use gapfilling for the new codes was announced. Based on our interactions with the contractors who are pricing the tests, we continue to have the same concerns about the fairness and transparency of the process. As a result, we are requesting the opportunity to meet with you and your staff to discuss our specific recommendations: *i.e.*, (1) CMS should instruct contractors to make available their data and methodologies to show how they arrived at their pricing determinations, and (2) CMS should convene an "Open Door Forum" to review the price-setting process for the remainder of the year and to respond to the numerous questions that have arisen.

As you will recall, the new pathology codes were added to the CPT Manual for 2012, but CMS delayed their implementation for a year so that it would have time to determine how best to implement them. During that process, ACLA urged CMS to use a cross-walking process to establish prices for the new molecular pathology codes, largely because it is the simplest and most transparent method for pricing the new codes and because these new codes represent existing well-established tests. However, in its November Notice of Final Payment Determinations, CMS determined that it would use the gapfilling process to price the new codes. At that time, ACLA expressed concern about the significant workload involved in this task, the short time in which contractors had to price the new codes, the relative inexperience of most contractors with gapfilling and molecular pathology, and the potential for a negative impact on patient care. In a November 30, 2012 letter to Acting Administrator Marilyn Tavenner, we requested that if CMS continued to require the contractors to use the gapfilling process, as an interim solution beginning January 1, 2013, the agency should provide cross-walk pricing for 2013 to allow sufficient time for the contractors to complete the gapfill pricing process and to ensure that laboratories continue to be paid for these services without disruption. Alternatively, we suggested that CMS could establish G-codes to replace the stacking codes and price them at the same level as the stacking codes, and laboratories could use the G-codes until the gapfilling

1100 New York Avenue, N.W. • Suite 725 West • Washington, DC 20005 • (202) 637-9466 Fax: (202) 637-2050

process was completed. We do not believe that it is too late for CMS to consider these alternatives, given the way the process is unfolding.

This far into the process, it is increasingly clear that there are major problems with how gapfilling is proceeding. Even though we are less than a week away from when prices must be reported to CMS—and almost two years from the time when the codes were first announced—the process is still far from complete, and significant questions persist about how contractors arrived at the prices that they have posted. For example, at this time, only Cahaba, Noridian, NGS and Palmetto have priced a substantial number of the new codes. CGS posted its proposed prices, which appear identical to those developed by Palmetto. Novitas has released only a handful of codes at this time, because, according to the contractor, it is not permitted to publish its prices before giving them to CMS. Nonetheless, the Novitas prices that are available are identical to those posted by Palmetto. Noridian has priced a substantial number of the codes; remarkably, its prices are exactly 89.5 percent of the price established by Palmetto. NGS and NHIC have priced only a handful of tests, supposedly because they have received claims for only those few. (Of course, if those contractors price only the tests as they receive claims, it raises significant questions about what happens if they have not received any claims for certain tests by March 31, when they have to report prices to CMS. Are the contractors' prices for those tests just not included when CMS posts prices at the end of April?) At this point, First Coast and Wisconsin Physician Services have not posted any prices and it is not clear when they will. Moreover, despite our requests, contractors have provided little background on how they arrived at the particular prices.

As a result, we continue to have significant concerns about the process, including the following:

- First, despite being less than a week from the time when contractors are required to report to CMS, there still are a large number of codes that have yet to be priced by some of the contractors. If the contractor has not yet priced the tests, then laboratories are not receiving payment for those codes. Noridian has told laboratories very specifically that it will not begin to pay for the tests until April because of a software problem, and Palmetto has instructed laboratories <u>not</u> to bill for tests that it has not yet priced, putting further financial pressure on laboratories that already are squeezed by a number of other reimbursement pressures. Even among those contractors that have priced most of the codes, there still are some for which no information is available and for which no payment is being made.

- Second, it is impossible to determine how contractors have arrived at the particular prices that they have posted or to replicate their pricing decisions. ACLA and other laboratory groups have had significant conversations with Palmetto, for which we are grateful, including an in-person meeting in Columbia, South Carolina this past week. However, it still is extremely difficult to determine how Palmetto arrived at its prices. Palmetto officials have stated that, after making certain adjustments, they averaged the pricing for the "code stacks" that laboratories previously used. Despite this explanation, however, we are not able to replicate the prices Palmetto has arrived at or even come close in most instances. If Palmetto simply averaged the code stacks previously used, then based on

our analysis, the prices should be significantly above the level at which they were set. Furthermore, Palmetto has stated that it has made adjustments to some of the code stacks used by laboratories, but we do not know what adjustments were made nor can we assess the reasonableness of what they did. Finally, as noted, many of the contractors appear to have relied in some way on the prices established by Palmetto, rather than performing the gapfilling themselves, thus making an understanding of how Palmetto arrived at its prices even more important (since one contractor's work essentially would result in a national limitation amount).

- We are equally confused by some of the other prices posted. For example, Cahaba appears to have established tiers of prices that it applied to most of the new codes. The tests almost all appear to be grouped into various price levels at the $50, $123, $235, $650 and $1,200 levels. However, there is no way to ascertain how the contractor arrived at those specific price levels or how it determined which tests to assign to which levels. We have reached out to Cahaba to discuss these questions but have been told they will not talk to us until the comment period that begins in May. Similarly, we cannot determine a basis for Noridian's apparent decision to price its tests at 89.5 percent of the Palmetto level, nor for other contractors' decisions simply to adopt the Palmetto prices. Indeed, the fact that so many of the contractors relied on Palmetto's prices seems to undercut the whole purpose of the gapfilling process which is designed to obtain input from numerous sources.

- Other pricing decisions also do not appear to have any basis. For example one contractor has stated that it adjusted the laboratory prices that it posted by the Geographic Practice Cost Index, which has no applicability to the Medicare Clinical Lab Fee Schedule ("CLFS") and is primarily used for adjusting physician prices, which vary by locality. The CLFS pays all tests in a particular contractor jurisdiction at the same level, without any adjustment for specific locations. Thus, it is difficult to understand why this adjustment would have been made. At a minimum, we should have the ability to review exactly what the contractor did with this information to the extent that it affected pricing.

- There is also widespread confusion about how the Tier 2 codes will be handled. The CPT Manual establishes nine broadly-defined "parent" codes, with specific test examples listed under each. While it is clear that it is the nine parent codes that are to be priced, one contractor has decided to instead price each individual component test. It is unclear how those individual prices will be used to establish the price for the parent code. Will it be an average, a median or something else? Another contractor has assigned a price—without any explanation—to each of the parent codes. It is a mystery how these different approaches will be reconciled when the time comes to establish a national limitation amount based on the median of all the contractor prices.

- In several cases, the prices established by the contractors are so low that they do not cover the cost of providing a test. We have heard from some of our laboratories that they may stop offering some of these tests to Medicare beneficiaries in the near future because of inadequate reimbursement, which would have a direct and obvious impact on beneficiary access.

- These numerous questions make it vitally important that interested stakeholders have the ability to review the analyses and data being relied on by the contractors. After CMS posts the contractor prices on April 30, there is a 60-day comment period required by the regulations. However, without more information on the processes used by the contractors, laboratories will be denied the opportunity to submit meaningful comments. We cannot be expected to explain our concerns about the way the prices were derived if we have no information to review. Furthermore, there are several contractors who have posted no pricing information or very limited pricing information at this time; thus, we have no ability to determine the basis for their pricing decisions. In other situations when CMS posts proposed prices, there is a plethora of background information made available to commenters. For example, when the proposed Physician Fee Schedule rule or the Outpatient Prospective Payment System rule is released, a significant amount of background data are presented that allow interested parties to determine the basis for the resulting price levels and to make informed comments. We believe that this gapfilling exercise requires a comparable process if laboratories and other stakeholders are to have a meaningful opportunity to provide their input during the upcoming comment period.

As a result, we are requesting that prior to the initiation of the comment period on May 1, 2013 contractors should be instructed to make available their methodologies and data that show how they arrived at their prices (including information about tests they excluded from pricing calculations). If necessary, we would be willing to work with CMS on identifying tests of particular importance so that it is not necessary to publish that information for the entire range of over one hundred codes. When directing contractors to make this information public, CMS must provide the contractors with parameters for how they present their work so that stakeholders have meaningful information to review. Again, without such information, stakeholders' right to comment is meaningless. We also believe that CMS should convene an "Open Door Forum" or stakeholders' meeting at that time to review the price-setting process for the remainder of the year and to respond to numerous other questions that have arisen about specific issues, such as those discussed above.

In our previous discussions relating to gapfilling, we were urged to be patient and were assured that the gapfilling process would be a transparent one. Unfortunately, we do not believe that has been the case, and we are concerned that the lack of transparency will continue to impede the ability of laboratories to comment meaningfully on the prices arrived at by contractors. As you can understand, this is a matter of great concern and seriousness to clinical laboratories. We look forward to discussing this with you further. Please contact me at your earliest convenience so that we can set up a time to meet.

Sincerely,

Alan Mertz
President

cc: Jonathan Blum