November 30, 2012

American Clinical Laboratory Association

Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Service
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Ms. Tavenner:

On behalf of the American Clinical Laboratory Association ("ACLA"), I am writing to express our serious concerns about the Centers for Medicare and Medicaid Services' ("CMS's" or "the agency's") intention to direct the Medicare Administrative Contractors ("MACs") to use gapfilling to establish prices for new codes for more than one hundred molecular pathology procedures. CMS's approach to these codes may have a serious adverse impact on independent clinical laboratories and erode the quality of health care for Medicare beneficiaries starting on January 1, 2013. We would like to meet with you in the near future to discuss our concerns and work with you to develop a reasonable path forward.

We continue to believe strongly that the best solution is simply to crosswalk the new codes to a weighted median of the prices paid for these tests in the past, as we have recommended previously. If CMS continues to require the MACs to use the gapfilling process, we request, as an interim solution beginning January 1, 2013, that CMS provide crosswalk pricing for 2013 to allow sufficient time for the contractors to complete the gapfill pricing process and to ensure that laboratories will continue to be paid for these services without disruption. Alternatively, and as a common-sense solution, CMS could establish G-codes to replace the soon-to-be-deleted stacking codes and price them at the same level as the stacking codes, and laboratories could use the G-codes until the gapfilling process has been completed.

ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories that provide hundreds of thousands of molecular pathology tests each year. If CMS does not alter its approach to pricing these codes and institute an interim solution, our member laboratories could experience a substantial disruption in reimbursement for molecular pathology tests in 2013. Furthermore, a number of laboratories may decide to cease providing these tests until pricing and reimbursement issues are resolved. This could have an adverse effect on beneficiary access to these critical tests and cause delays in diagnosis and treatment. Because the current CPT codes used to bill for these services will be deleted as of January 1, 2013, and neither CMS nor the Medicare contractors have priced any of the more than one hundred new molecular pathology codes yet, laboratories cannot be paid for these services until contractors price them. There is not sufficient time before January 1, 2013 for contractors to complete this complex gapfilling process for all of these new codes.

A. Background

The 2012 and 2013 CPT code manuals added 114 new CPT codes for molecular pathology services, which are complex analyses of genetic and genomic information and play a

crucial role in the development of many personalized medicine tests. The new CPT codes are divided into two groups: Tier 1 codes describe gene-specific and genomic procedures; Tier 2 codes are not gene-specific but rather describe different levels of technical resources and interpretive work required for molecular pathology procedures not included in Tier 1. Each Tier 2 code describes numerous tests, and some Tier 1 codes describe multiple tests or variations thereof, as well.

As CMS has acknowledged, the molecular pathology services represented by the new CPT codes are not new *tests*; only the *codes* are new. For two decades, molecular pathology tests have been billed using a combination of longstanding CPT codes that describe each of the various steps required to perform a given test. This billing method is called "stacking" because different "stacks" of codes are billed depending on the components of the fundamental test. The stacking codes are to be replaced on January 1, 2013 with the new CPT codes, and the existing stacking codes will be deleted. Although many of the new CPT codes actually were effective in 2012, CMS delayed pricing the codes at that time because of the large number of new codes and the complexity of the pricing exercise. It stated at the time that it would instead price the codes for 2013.

According to federal regulations, CMS has two options when determining how to price a clinical diagnostic laboratory test that is assigned a new or substantially revised code: crosswalking or gapfilling.[1] Crosswalking is to be used when, as with the molecular pathology tests, "it is determined that a new test is comparable to an existing test, multiple existing test codes, or a portion of an existing test code."[2] When CMS uses crosswalking, it assigns to the new test code the lesser of the local fee schedule amount or the national limitation amount for the existing test. In its comments on the Medicare Physician Fee Schedule Proposed Rule for CY 2013, ACLA recommended that CMS crosswalk the molecular pathology codes to a fair weighted median price based on historical pricing of the tests using stacking codes. Because each laboratory has performed the tests in a slightly different way, and there is no one way that is "more right" than another, the stacking codes billed and the reimbursement received often have differed among laboratories. Therefore, ACLA encouraged CMS to use historical billing data to find a weighted median price for the tests. This is very similar to the approach that CMS uses in other contexts, such as when it establishes national limitation amounts for the Clinical Laboratory Fee Schedule.

The gapfilling process, on the other hand, is to be used "when no comparable existing test is available." Gapfilling has been used extremely rarely and only for new tests that have very low volume initially and that have not been covered by Medicare in the past. Despite the fact that the new molecular pathology codes describe existing tests, not new tests, CMS chose the gapfilling method for pricing the tests. In an announcement posted on the CMS website on November 6, 2012, CMS stated that Medicare contractors would gapfill the new test codes for payment beginning on January 1, 2013. We continue to disagree strongly with using gapfilling to price existing tests and welcome your reconsideration of this decision. Furthermore, as of today, we are unaware of any instructions that CMS has transmitted to the MACs establishing parameters for pricing the codes.

[1] 42 C.F.R. § 414.508.
[2] 42 C.F.R. § 414.508(a).

B. The remaining time in 2012 is wholly inadequate for contractors to gapfill more than one hundred new codes.

Even though the new test codes were adopted in the American Medical Association ("AMA") CPT code manual in 2012, the decision to gapfill the new codes was just announced. It is only five weeks prior to the start of CY 2013, and just one Medicare contractor has begun to collect information from laboratories systematically in order to proceed with the gapfilling process. As a whole, Medicare contractors have very little experience with gapfilling; the process requires gathering and analyzing a great deal of data from all providers of these services, and contractors will have to engage in this unfamiliar and complex process for more than one hundred codes simultaneously. Furthermore, particularly for the Tier 2 codes, contractors will need to gather information on multiple tests for each new code. This task is unprecedented, and given the few weeks allotted, impossible to complete.

The AMA, which "owns" the CPT codes, made the new molecular pathology codes effective for January 1, 2012, although CMS did not price the new codes at that time. As far back as July of 2011, ACLA cautioned CMS that the AMA had initiated "a massive coding and valuation reconfiguration that will impact over 100 clinical laboratory molecular pathology services" and asked that "no action in this area be finalized until 2013 to allow for the needed clinical laboratory operations transition and to minimize impact on Medicare beneficiaries."[3] ACLA met with CMS about this very issue beginning in early 2011. ACLA already was aware, and communicated to the agency, that the coding and valuation for the new codes would be an enormous undertaking that would require a tremendous amount of time and collaborative work. Nevertheless, we now find ourselves in the very position that we were hoping to avoid.

Five weeks is an inadequate amount of time for one contractor to gapfill even one code thoughtfully and with substantive input from affected stakeholders, let alone more than one hundred codes. We are concerned that many contractors are not familiar with the process due to its infrequent use and may not have the institutional memory and staff expertise to complete such a process in a timely manner for so many new codes. The complexity of the task and the quantity of new codes involved also increase the likelihood that the prices that contractors establish initially will not reflect the true costs of providing the molecular pathology services.

C. Currently, there is no way for laboratories to be reimbursed for molecular pathology tests starting on January 1, 2013, which could result in substantial reimbursement delays.

Until Medicare contractors complete the gapfilling process, in many cases, laboratories cannot be paid for the molecular pathology services with the new CPT codes. Typically, when gapfilling has been used in the past, the impact has been smaller, because new tests naturally have low claim volumes. In contrast, here, gapfilling would be used for well-established and frequently-ordered tests, and payments would be delayed while multiple Medicare contractors establish prices. This is unfair to laboratories and comes on top of severe cuts to fee schedules.

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[3] ACLA Comments to CMS on New AMA CPT Molecular Pathology Codes (July 18, 2011), *available at*: http://acla.com/comments-testimony-letters .

If laboratories are unclear about when and how much they will be paid for the molecular pathology tests, some may stop providing them altogether until prices are set. Physicians who rely on these tests will lose valuable diagnostic tools, and Medicare beneficiaries will lose access to tests that would guide their treatment.[4] (As you are aware, laboratories cannot provide anything beyond a *de minimis* value to Medicare beneficiaries for no charge whatsoever, yet there will be no way to bill the Medicare program for the tests, either.)

D. While we continue to believe that the best approach is crosswalking, we recommend that CMS provide an interim payment amount by January 1, 2013, such as a nationally-established weighted median based on historical reimbursement, if CMS continues to require the gapfilling process and until it is completed.

We believe that the best solution is for CMS to use the crosswalk process to establish fair and budget-neutral pricing. If CMS continues to require contractors to establish pricing using the gapfilling process, a reasonable solution is to establish interim payment amounts for the new CPT codes to allow contractors sufficient time to engage in a thoughtful, collaborative gapfilling process. As ACLA has recommended in the past, a fair and budget-neutral approach would be to establish national interim payment amounts that are equal to the weighted median of the prices the agency has paid historically for the tests. CMS has adequate data (including crosswalk data previously submitted to CMS by ACLA member laboratories) to determine such an amount for each test, and it should not be administratively complicated to communicate the amounts to all of its contractors and to laboratories. Alternatively, CMS could establish G-codes to replace the soon-to-be-deleted stacking codes and price them at the same level as the stacking codes, and laboratories could use the G-codes until the gapfilling process has been completed.

Although we believe that the crosswalk process is both more appropriate for existing tests and less arbitrary than gapfilling, we believe it would be possible for most Medicare contractors to complete the gapfilling process within six months to a year, so that by January 1, 2014, the new molecular pathology codes are priced and the contractors' systems are ready to process claims for them.

E. Conclusion

ACLA is concerned that the short time remaining in 2012 for pricing the new CPT codes makes an already complicated process even more difficult to accomplish, and the result will be that laboratories, through no fault of their own, may not be paid for molecular pathology tests until Medicare contractors are able to complete the gapfilling process for the new codes. We believe that process may take months to complete.

We urge you either to reconsider the decision to follow the gapfilling process or, at the very least, to implement our proposed interim solution for temporary rates based on crosswalking in order to avoid payment disruptions for laboratories and access disruptions for Medicare

[4] We note that commercial health plans are heavily influenced by Medicare coding and pricing decisions, and most commercial payors are unprepared to adopt and/or price the new codes by January 1, 2013.

beneficiaries. Unlike the gapfilling process currently planned, crosswalking can be implemented by January 1, 2013 when the stacking codes are deleted. Alternatively, and as a common sense solution, CMS could establish G-codes to replace the soon-to-be-deleted stacking codes and price them at the same level as the stacking codes, and laboratories could use the G-codes until the gapfilling process has been completed. We are available to discuss this situation with you at your convenience. Thank you for your attention to this matter.

Sincerely,

Alan Mertz
President

cc: Jonathan Blum
Marc Hartstein