



American
Clinical Laboratory
Association

December 31, 2013

Jonathan Blum
Principal Deputy Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Blum:

On behalf of the American Clinical Laboratory Association (“ACLA”), we are writing to express our strong objection to CMS’s recent action establishing a new reduced price for CPT code 81211 (BRCA1 and BRCA2 sequencing) as part of the gapfill price-setting process. As discussed below, we believe that CMS’s action to reduce the final gapfill payment rate by almost fifty percent is a plain violation of the agency’s own gapfilling regulations and therefore must be retracted.

As you know, CPT 81211 (BRCA1/2 sequencing) was one of the over one hundred CPT molecular pathology codes that CMS determined would be priced in accordance with the gapfilling requirements of 42 C.F.R. §§514.508 and 514.509. As required by that process, contractors spent the first quarter of the year determining their prices for these codes, which CMS then posted on a preliminary basis in May. After reviewing public comments on those prices, contractors submitted final gapfill prices, which CMS posted on September 30, along with the medians of the prices. Under CMS regulations, these medians become the National Limitation Amounts (NLA) at which the tests are paid in 2014. In the September 30 posting, CMS published an NLA of \$2795.09 for CPT code 81211. Then, on November 29, without explanation, CMS reduced the price for that code to \$1438.14. After objections from ACLA and its members, on December 27, CMS announced that it would permit an additional 30-day comment period to allow stakeholders to comment on the new price. CMS also states that the price of \$1438.14 will be effective January 1, but that it could be changed based on the comments received, effective April 1, 2014.

CMS’s action with regard to this code is wholly unsupported by its own regulations or other precedent. In fact, the new 30-day comment period is not referenced in the CMS gapfilling regulations and CMS’s explanation for its action is extremely vague. It suggests that following the Supreme Court’s decision this summer, additional laboratories began to offer the test. It then states that “The MACs received pricing by the other laboratories offering the test. Based on the new information, the MACs submitted pricing information on CPT code 81211 that resulted in an NLA of \$1438.14.”

However, under CMS regulations, the price established in the September 30 posting is to be the final price for 2014, unless CMS acts on a written request for reconsideration.¹ CMS does not state that it received such a request nor is ACLA aware of such a request being filed.² CMS suggests that its decision was precipitated by the Supreme Court’s decision involving BRCA patents and the announcement that other laboratories stated they would begin to offer the test.

¹ 42 CFR §414.509(b)(2)(iii)-(iv).

² As noted below, ACLA also requests copies of any such reconsideration request or other information received by CMS or the contractors that form the basis for this decision.

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However, the Supreme Court decision was issued in June, 2013, long before CMS posted its final decision. Moreover, neither this Supreme Court decision nor the announcement that other laboratories would offer the same test justifies CMS's decision to ignore its own detailed gapfilling regulations. Further, it does not appear that \$1438.14 even represents the median of the published prices for 81211; thus there is no way to determine the basis or appropriateness of CMS's price setting decision.

This action is only the most recent example of the capriciousness and lack of transparency, which, in the industry's view, has characterized much of the gapfilling process throughout the year. As explained above, there is no basis for CMS's decision to pay at the new reduced price beginning January 1. We therefore urge CMS to reinstate the final gapfill price of \$2795.09 for CPT Code 81211, as was posted on September 30, to be effective January 1, 2014. If CMS decides to go forward with the special comment period, then CMS should make available immediately any request for reconsideration and other information on which it based its action reducing the price. We believe it is only fair that interested parties have the opportunity to review this information, so that they can respond to any errors or other data when submitting their own comments.

Thank you for your assistance with this issue. If you have any questions or need any additional information, do not hesitate to contact me.

Sincerely yours,

A handwritten signature in cursive script that reads "Alan Mertz".

Alan Mertz
President

Cc: Marc Hartstein, CMS