



American
Clinical Laboratory
Association

January 24, 2014

Mr. Marc Hartstein, Director
Hospital and Ambulatory Policy Group
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 31344

MoPathGapfillInquiries@cms.hhs.gov

RE: Notification of Reconsideration Period – 2013 Gapfill Payment Amounts

Dear Marc,

Please accept the comments of the American Clinical Laboratory Association (“ACLA”) on the Notification of Reconsideration Period – 2013 Gapfill Payment Amounts for molecular pathology tests, specifically for CPT code 81211 (BRCA1, BRCA2) (“81211”).¹ As you know, 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 and Medicaid patients each year, ACLA member companies have a direct stake in ensuring that prices for molecular pathology testing services are developed openly, rationally, and in conformance with CMS’s own rules, and that the pricing levels represent reasonable compensation for developing and furnishing the services.

In sum, CMS has violated its own gapfilling rules in several respects, and the final payment amount for 81211 of \$2,795 should be reinstated effective January 1, 2014. There is no regulation that would permit CMS to establish a gapfill reconsideration period in the manner and for the reasons it has done so. Additionally, CMS has failed to follow its own regulation with respect to the final gapfill price for 81211, and its actions have resulted in an unsupportable decrease in the payment amount of almost one half for 2014. CMS should reinstate the original final amount effective January 1, 2014.

A. Background for Gapfilling CPT Code 81211

Early in 2013, Medicare Administrative Contractors (“MACs”) established interim prices for 81211. CMS published for each of the MACs’ prices in early May 2013, and the public had 60 days to submit comments to CMS. After CMS received all public comments and consulted with each of the MACs, CMS published the MACs’ final gapfill prices for 81211 in an Excel spreadsheet on September 30, 2013. According to CMS’s regulations, these were to be final

¹ Notification of Reconsideration Period – 2013 Gapfill Payment Amounts, Clinical Laboratory Fee Schedule (CLFS), available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html> (last visited Jan. 24, 2014).

MAC-specific amounts. The spreadsheet also indicated a median price for 81211 of \$2,795, which is the National Limitation Amount (“NLA”).²

CMS posted an Excel spreadsheet on its website on November 29, 2013 with the Clinical Laboratory Fee Schedule (“CLFS”) NLAs. Inexplicably, the NLA for 81211 was slashed from \$2,795 to \$1,438. CMS did not alert the public that it had reconsidered the final September 2013 price and did not provide any reason for the price reduction of almost 50 percent.

On December 27, 2013, CMS took the unusual step of posting a Notification of Reconsideration Period for CPT code 81211 and two other codes. It acknowledged the higher final amount it posted for 81211 on September 30, 2013 and the lower amount of \$1,438 it posted on November 29, 2013, stating that the lower amount “was based on the median of MAC-submitted prices and will be effective for tests performed on or after January 1, 2014.” CMS then discussed an issue that is wholly irrelevant to the gapfilling process as set forth in federal regulations, a Supreme Court decision on patent issues associated with CPT code 81211. It said,

Following the Supreme Court decision, additional laboratories began providing the test. The MACs received data on the pricing by the laboratories offering the test. Based on the new information, the MACs submitted pricing information for CPT code 81211 that resulted in an NLA of \$1,438.14. As the public has not had the opportunity to provide comment on the new NLA for 81211 we are providing an additional public comment period through January 27, 2014. At present, it is our understanding [that] laboratories are offering the CPT code 81211 test for prices that range from approximately \$900 to \$2,900. As CPT code 81214 is similar to CPT code 81211, the additional 15-day comment period will apply to both CPT codes 81211 and 81214.

CMS did not say when the MACs received more pricing information for laboratories now performing the test; presumably, it was after the September 30 final gapfill prices. CMS stated that the NLA may change as a result of comments received pursuant to this extra comment period and that “Medicare contractor comments may also form the basis for a change in the NLA.”

² Per CMS’s gapfilling regulations, in the first year, a test code is paid at contractor-specific amounts; in the second year, the test code is paid at the national limitation amount, which is the median of the contractor-specific amounts. *See* 42 C.F.R. § 414.508(b). We note that Palmetto GBA’s final amount for 81211 (BRCA 1&2) was \$1,499, the same final amount it set for CPT code 81214 (BRCA1). Palmetto officials shared with some of our members that they selected this rate for 81211 because they were unconvinced of the clinical utility of BRCA2, so they reduced the price of the BRCA1&2 test to the value for the test only for BRCA1.

B. CMS Has Violated Its Own Gapfilling Regulations

1. CMS May Reconsider Final Amounts Only in Limited Circumstances Not Evident Here

CMS's gapfilling regulations state that by April 30 of a year, CMS posts interim contractor-specific amounts on the CMS website. CMS then receives public comment on the interim amounts for 60 days, after which it is to post final contractor-specific amounts.³ Then, "[f]or 30 days after CMS posts final [contractor]-specific amounts on the CMS Website, CMS will receive reconsideration requests in written format regarding whether CMS should reconsider the final payment amounts and the appropriate national limitation amount for the new test."⁴

We are unaware of a request for consideration from the public "in written format." Despite having asked CMS for information about such written request, ACLA has not received any indication who may have submitted one, if one was submitted. If a written reconsideration request was filed with CMS, we urge the agency to make public an unredacted copy of the request. CMS said in its December 27, 2013 reconsideration notice only that it established the lower amount of \$1,438 for 81211 after "the MACs received data on the pricing by the laboratories offering the test" and that "based on the new information, the MACs submitted pricing information for CPT code 81211 that resulted in an NLA of \$1,438." In no way does that scenario conform to CMS's own regulations for reconsideration of a final gapfill price for a test.

CMS's reference to additional information submitted by MACs may mean that a MAC submitted a request for consideration, in writing or orally. However, in other contexts in the Medicare program, a contractor is not among "parties to a reconsideration," per CMS's regulations governing reconsiderations.⁵ Furthermore, the preamble to the final rule in which the gapfilling regulations were promulgating stated that the purpose of the reconsideration process is to "balance additional opportunities for public input against the necessity for establishing final fees for new clinical laboratory test codes."⁶ It would be illogical for CMS to (1) share public comments on the contractors' interim amounts with the contractors for the contractors' consideration, (2) to arrive at final contractor-specific prices by September 30, and (3) allow contractors to request reconsideration of their own final prices.

The September 30, 2013 notice with final amounts is itself evidence of the fact that reconsideration requests are expected from laboratories furnishing the tests at issue, not from the contractors pricing them:

The public will have 30 days to request reconsideration of the NLAs listed in the September web posting...You may copy your MAC on your comment to CMS; however, please do not comment directly to your MAC without including CMS on your submission. Please provide the following

³ 42 C.F.R. § 414.509(b)(2).

⁴ 42 C.F.R. § 414.509(b)(2)(iv).

⁵ These include beneficiaries, suppliers, providers, a State Medicaid agency, and certain non-participating physicians who may be liable to refund monies. *See* 42 C.F.R. § 405.906(b).

⁶ 72 Fed. Reg. 66276 (Nov. 27, 2007).

specific information about your test if you wish it be considered for reconsideration: test Methodology (*e.g.*, Real-time Quantitative PCR (RQ-PCR), Reverse-transcription PCR (RT-PCR), flow cytometry, capillary electrophoresis, fragment analysis etc.); specific cost per sample (specify reagent, direct labor costs, equipment costs, indirect costs, etc.).

A contractor could not copy its MAC on a comment to CMS, nor could it provide CMS with specific information about its test, such as test methodology or the specific cost per sample. Clearly, reconsideration requests are expected to come from laboratories performing tests at issue, not from contractors. This statement from the September 30 notice with final amounts also calls into question CMS's statement in the December 27 Notice of Reconsideration Period that "Medicare contractor comments may also form the basis for a change in the NLA." Plainly, when CMS posted final amounts on September 30, it did not contemplate comments from contractors influencing a reconsideration of NLA prices.

We believe that CMS's December 27, 2013 reconsideration notice violates CMS's own regulations because we are unaware that CMS ever received a written request for reconsideration of CPT code 81211 from a "party to reconsideration," as that term is defined in CMS's regulations.

2. Allowing This Process to Stand Would Set a Dangerous Precedent for Medicare Contractors Participating in Gapfilling

We are concerned that if CMS permits this extra-regulatory process to stand, it will set a bad precedent for future gapfilling cycles and embolden CMS and its contractors to ignore final prices. A contractor, with tacit approval by CMS, could reduce a payment amount after a final amount is made public and a median is established. Or, a contractor could "collect more data" after a final amount is made public (whether it seeks the data or whether it is unsolicited), develop a new price, and urge CMS to lower the final amount. Especially because this is the first time that CMS has gapfilled a large number of tests at once, and given that more and more novel molecular pathology tests will need to be gapfilled in the future, CMS should take care not to establish a pattern of ignoring its own rules for the gapfilling process.

C. The New Proposed Median Is Not a Median At All

The NLA that CMS posted for CPT code 81211, which is supposed to be the median of the carrier-specific amounts,⁷ is not such a median at all. On November 27, 2013, CMS posted an NLA of \$1,438. We surveyed ACLA member laboratories that offer the test, and each one of their Medicare charges exceeds this posted NLA. The median we have calculated is roughly two times the posted NLA, and it is approximately the same as the median price posted on September 30, 2013. This is another way in which CMS has violated its own regulations, and the agency must explain how it developed an NLA – a median of the carrier-specific amounts – that bears no resemblance to the actual median prices of laboratories performing the test.

⁷ 42 C.F.R. § 414.508(b)(2).

D. The Differences Between CPT Code 81211 and CPT Code 81214 are Significant Enough to Justify Different Prices

In its December 27, 2013 Notice of Reconsideration Period, CMS stated that CPT code 81214 is similar to CPT code 81211, and it assigned the same NLA of \$1,438 to both tests. ACLA disagrees with this approach. Although the tests are related, the resources and time associated with them is different.

Given the difference between the two codes, the correct price for CPT code 81214 cannot also be the correct price for CPT code 81211. The test represented by CPT code 81214, BRCA1, is a component of the test represented by CPT code 81211, BRCA 1&2.⁸ CPT code 81214 does not include sequencing analysis on BRCA2. This is significant difference, as a BRCA test that does not include BRCA2 sequencing is not adequate for a comprehensive BRCA test for some individuals. If a patient were to have a BRCA test without BRCA2 sequencing, the patient still would be at risk of having a mutation in BRCA2 and would need to be tested for BRCA2 mutations. Furthermore, as BRCA testing is very involved, the resources required for additional testing for BRCA2 are not insignificant. Such testing requires additional technical sequencing, technical analysis, and a thorough and robust process for clinical interpretation of the result. This interpretation step is especially important for BRCA testing with the high number of possible mutations in the BRCA1 and BRCA2 genes and the possibility of not being able to identify the significance of the mutation (variant of unknown significance) without a high quality and involved annotation service. For these reasons, it would be inappropriate to try to justify such a low price for CPT code 81211 by claiming that the test is similar to 81214.

E. The Final Median Amount of \$2,795 Should Be In Effect As of January 1

Regardless whether CMS agrees with ACLA's conclusion that the additional comment period violates of the agency's own regulations, the amount that should be in effect as of January 1, 2014 for 81211 is the final amount of \$2,795, not the inexplicably revised November 29, 2013 amount of \$1,438. Per CMS's gapfilling regulations, the amount paid in the second year for a test – in this case, 2014 – is the NLA, the median of contractor-specific amounts.⁹ This is the final price for 81211 set forth in the September 30, 2013 release, \$2,795, not the price that was posted on November 27, 2013. CMS's gapfilling regulations do not allow for a "new NLA," which is how the agency described the lower amount of \$1,438, and the original final amount of \$2,795 should be reinstated unless and until CMS has a valid basis on which to adjust the price for 81211 upward or downward.

⁸ The description for CPT code 81214 is "BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)." The description for CPT code 81211 is "BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BRCA1 (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)."

⁹ 42 C.F.R. § 414.508(b).

F. Conclusion

ACLA does not believe that CMS is acting within its authority in reconsidering the final amount for 81211 as established through the gapfilling process, absent a written request from a legitimate party to a reconsideration process. The agency has considered events and data that are not relevant to the gapfilling process as set forth in its own regulations, and the initial final payment amount for 81211 of \$2,795 should be reinstated as of January 1, 2014.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink, consisting of a large, stylized initial 'J' followed by a long horizontal line that ends in a small hook.

JoAnne Glisson, Senior Vice President
American Clinical Laboratory Association