January 27, 2014

VIA EMAIL:  MoPathGapfillInquiries@cms.hhs.gov

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re:  Gapfill Process and Resulting Payment Amounts

Dear Ms. Tavenner:

On behalf of the members of AdvaMedDx, I am writing to express concern regarding recent actions taken by the Centers for Medicare & Medicaid Services (CMS) in establishing payment amounts under the Clinical Laboratory Fee Schedule using a gapfilling process.

AdvaMedDx, operating as a division of the Advanced Medical Technology Association (or AdvaMed), represents the world’s leading diagnostics manufacturers by advocating for the power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and abroad. AdvaMedDx member companies produce innovative, safe and effective diagnostic tests that facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and often reduce health care costs.

AdvaMedDx has commented on several occasions regarding the appropriateness of the payment amounts resulting from gapfilling, which factored into the assignment of national pricing amounts in 2014. Current Medicare regulations require that, for the first year of gapfilling, specific amounts are established for each Medicare Administrative Contractor (MAC) using multiple sources of information (charges for the test, resources required to perform the test, payment amounts made by other payers, and payment amounts for comparable tests).\(^1\) In the second year, a national amount is established based on the median of the MAC-specific amounts.\(^2\)

For a large number of molecular diagnostic tests, CMS followed gapfilling procedures during 2013 to establish payment rates for 2014. During the spring and summer of 2013, CMS

\(^1\) 42 CFR 414.508(b).
\(^2\) Id.
collected payment information from Medicare contractors and in September established National Limitation Amounts (NLAs), or payment amounts, for these tests.

For CPT code 81211 (BRCA1 and BRCA2 sequencing), CMS established a NLA of $2,795.09. In November, 2013, however, CMS without explanation posted a NLA of $1438.14 for 81211, a reduction of almost 50 percent. This change was unexpected and some stakeholders assumed and were lead to believe that it was a clerical error on the part of one contractor and that it would be “corrected.”

On December 27, 2013, CMS posted an update on its website, clarifying that the reduction was not the result of a clerical error, but was due to new information received by Medicare contractors about availability of BRCA tests subsequent to a Supreme Court decision earlier in the year.

While we appreciate the Agency’s need to deal with changes in the landscape that could have substantial effects on Medicare payment rates, it is equally important that CMS follow a clear and transparent process that is well understood by stakeholders, including diagnostic test manufacturers and laboratories.

The lack of transparency regarding the revised payment rate leads us to question the posted payment amount. During 2013, as the gapfilling process was underway, the various Medicare contractors posted payment amounts for the codes being reviewed on their websites, as did CMS at a later stage in the process. Although this information was imperfect due to missing or incomplete data, it did provide the public with some notion of what the final payment amounts might look like.

In the case of CPT 81211, CMS provided limited information in its December 27 posting, stating that the MACs received pricing data by laboratories offering the test, ranging from $900.00 to $2,900.00. Without more information on a MAC-specific basis, it is not clear that the revised payment amount represents, as required, the median of the MACs’ payment amounts. In the interest of fuller transparency, we believe CMS should provide additional information on this point.

In this instance, CMS acted outside of the usual process, citing new information to justify its actions. The process, among other things, provides certain protections for stakeholders, such as transparency and the opportunity to provide feedback. While CMS has provided a 30-day comment, the Agency has not been forthcoming regarding the details of the new information on which it based the decision to reduce a payment rate by almost 50 percent.

CMS’s lack of transparency and the irregular actions outside of the usual process magnify our concerns for future rate-setting for laboratory services, particularly considering that later this year CMS will begin to reassess and potentially change payment amounts for all codes paid on the Clinical Laboratory Fee Schedule. To date, very little detail has been provided regarding the
process that the Agency will use to accomplish this goal. We believe CMS should use an orderly and transparent process that includes adequate opportunity for stakeholder input.

We appreciate the opportunity to comment on this very important issue. Please do not hesitate to contact me or Chandra Branham, J.D., Vice President, Payment & Health Care Delivery Policy, at (202) 434-7219 or cbranham@advamed.org if you have questions or need any additional information.

Sincerely,

[Signature]

Donald May
Executive Vice President
Payment & Health Care Delivery Policy
Advamed

Cc: Jonathan Blum
   Liz Richter
   Marc Hartstein
   Christina Ritter

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