October 30, 2013

Mr. Marc Hartstein, Director
Hospital and Ambulatory Policy Group
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
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MoPathGapfillInquiries@cms.hhs.gov

RE: Final 2013 Gapfill Payment Amounts for Molecular Pathology Tests

Dear Marc,

Please accept the comments of the American Clinical Laboratory Association ("ACLA") on the final 2013 Gapfill Payment Amounts for Molecular Pathology Tests.[1] 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 and rationally and that the pricing levels represent reasonable compensation for developing and providing the services.

ACLA's comments address process issues and legal issues related to the gapfill payment amounts. We understand that ACLA member companies are submitting reconsideration requests with respect to pricing for individual tests, including BRAF (CPT code 81210), CYP tests (CPT codes 81225-81227), SNPs (CPT code 81229), EGFR (CPT code 81235), JAK2 (CPT code 81270), KRAS (CPT code 81275), MLH1 (CPT code 81292), MSH2 (CPT code 81295), and MSH6 (CPT code 81298). These and other codes remain significantly underpriced. Without adequate reimbursement for these codes, laboratories across the country will have to make tough choices about the type of testing they can afford to offer Medicare and Medicaid patients, and patient access to these tests could be compromised. Our members have stipulated that several molecular diagnostic test codes still have rates below the actual cost of providing the tests. We hope that CMS will consider issuing new prices for these tests based on the cost data that is submitted by laboratories and other stakeholders as part of this reconsideration process.

[1] 2013 Gapfill Payment Amounts for Molecular Pathology Tests, *available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html.

A. Reconsideration of Missing Test Prices

When CMS released the final payment amounts on September 30, 2013, no prices were provided for 51 of the 116 codes.[2] However, several contractors provided interim prices to CMS for these codes earlier in the year, and CMS posted those carrier-specific interim prices in May. CMS has stated that its reason for not posting final prices for this group of tests is that the codes are not being paid by the Medicare Administrative Contractors ("MACs"). This erroneously conflates a coverage determination with the gapfill pricing exercise. Furthermore, state Medicaid programs need to know what amount Medicare would pay in order to comply with federal Medicaid law. We request that CMS reconsider its decision not to price these tests at all and, instead, to develop national limitation amounts ("NLAs") derived from the interim contractor prices.

Regardless of a MAC's decision whether to cover a molecular pathology test and whether to publish a Local Coverage Determination to that effect, all tests should have been priced by contractors. Indeed, the Medicare Clinical Laboratory Fee Schedule ("CLFS") includes prices for tests that are almost never covered for Medicare beneficiaries (*e.g.,* CPT code 81025, urine pregnancy test). Although CMS states that it did not price some codes because MACs are not covering those codes, the agency itself seems to have acknowledged that there is no relationship between establishing a price and determining coverage: "The inclusion of a code and/or payment amount for a particular clinical diagnostic laboratory test does not imply that the test will be covered under the Medicare program."[3]

The gapfilling regulations at 42 C.F.R. § 414.500 that set forth how CMS is to determine payment rates for new tests are devoid of any mention of the coverage status of a test. By regulation, the NLA for a test in the second year is "the median of the carrier-specific amounts" for a test. It is not "the median of the carrier-specific amounts provided by carriers who have decided to cover the test."[4] Effectively, CMS has determined that the NLA for this group of tests is $0, but that bears no relationship to prices that, by regulation, are supposed to be based on "(i) charges for the test and routine discounts to charges; (ii) resources required to perform the test; (iii) payment amounts determined by other payers; and (iv) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant."[5] Further, the regulations that set forth the procedures and timelines for posting carrier-specific interim payment amounts, receiving public comment on those payment amounts, and posting final carrier-specific amounts does not permit CMS to remove an already-posted carrier-specific interim payment amount when a carrier determines not to cover a test.[6] Despite this, CMS posted carrier-specific payment amounts in May and subsequently has removed prices for the tests.

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[2] The unpriced tests are represented by CPT codes 81161, 81200, 81201, 81202, 81203, 81205, 81209, 81216, 81220, 81221, 81222, 81223, 81224, 81228, 81229, 81242, 81243, 81244, 81250, 81251, 81252, 81253, 81254, 81255, 81257, 81260, 81266, 81280, 81281, 81282, 81290, 81302, 81303, 81304, 81324, 81325, 81326, 81330, 81331, 81350, 81355, 81400, 81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408, and 86152.

[3] 2013 Gapfill Payment Amounts for Molecular Pathology Tests.

[4] 42 C.F.R. § 414.508(b)(2).

[5] 42 C.F.R. § 414.508(b)(1).

[6] *See* 42 C.F.R. § 414.509(b)(2).

It is critical that CMS price all molecular pathology tests, regardless of whether or not they are to be covered in the Medicare program. By law, state Medicaid programs must limit payment for clinical laboratory tests to the amount paid in the Medicare program. The part of the federal Medicaid law that limits what state Medicaid programs may pay for items and services reads: "Payment…shall not be made…with respect to any amount expended for clinical diagnostic laboratory tests performed by a physician, independent laboratory, or hospital, to the extent such amount exceeds the amount that would be recognized under section 1395l(h) of this title for such tests performed for an individual enrolled under part B of subchapter XVIII of this chapter."[7] This provision limits Medicaid payment for laboratory tests to the amounts paid by the Medicare program. A state Medicaid program cannot comply with this requirement and limit its own reimbursement for molecular pathology tests without knowing "the amount that would be recognized" by the Medicare program. It certainly is outside of the scope of the MACs' responsibilities effectively to decide that Medicaid programs may pay no more than $0 for certain molecular pathology tests. Additionally, oftentimes, state Medicaid programs reimburse laboratories at a rate that is a percentage of the published CLFS amount, and private payors also take cues from Medicare prices when establishing reimbursement for laboratory tests.[8] Without a price for a test, it is less likely that state Medicaid programs and private payors will pay for a molecular pathology tests at all, or if they do pay for the test, to establish a fair price.

In the absence of fair pricing that covers the cost of tests, some laboratories could discontinue providing some tests to Medicare and Medicaid patients, and some laboratories could stop providing the tests altogether. We do not believe it is CMS's intention to limit beneficiary access to the unpriced tests, but that may be the effect of CMS's pricing choices.

CMS should price all of the 51 unpriced tests, regardless of coverage status, using interim prices previously provided by the MACs. This is consistent with CMS's treatment of other non-covered or rarely covered tests.

B. National Limitation Amounts

When CMS initially released the final gapfilling prices on September 30, 2013, it included this statement: "If CMS revises any NLAs as a result of the reconsideration process, the revised NLA will be the upper limit on payment beginning 1/1/2014. If an individual MAC establishes a price that is lower than the NLA, it may continue to pay that price in 2014." As you know, gapfilling regulations do not permit a MAC to pay a price that is lower than the NLA.[9] In the preamble to the final rule that established the gapfilling methodology, CMS itself said that the establishment of the NLA in the second year "would result in consistent payment in geographic areas for a new test using the median of the carriers' gapfilled amounts" and that prices are to be consistent between and among the MACs.[10]

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[7] 42 U.S.C. § 1396b(i)(7). 42 U.S.C. § 1395l(h) is the section of the Medicare statute establishing the CLFS.

[8] We know of at least 17 state Medicaid programs that peg their rates for laboratory services to the Medicare fee schedule, ranging from 70 percent to 100 percent of the amount paid under the fee schedule.

[9] *See* 42 C.F.R. § 414.508(b)(2).

[10] Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and

Although CMS removed the statement that would have permitted MACs to continue to reimburse at prices lower than the NLA in 2014, what has been left on its website has the potential to cause confusion among the MACs and result in inadequate reimbursement for laboratories for some molecular pathology tests. The statement that currently appears on the CMS website is this: "If CMS revises any NLAs as a result of the reconsideration process, the revised NLA will be the upper limit on payment beginning 1/1/2014." This sentence, combined with the previous instructions that would permit MACs to pay lower prices, leaves the impression that MACs *may pay any price up to and including the NLA* in 2014. This is in direct conflict with the regulations that require that MACs *must pay the NLA* in 2014, as required by the regulations.

We request that CMS issue a statement that clarifies for all parties that in 2014 and beyond, all MACS must pay the NLA for gapfilled molecular pathology tests, regardless of whether their own gapfilled prices are below the NLA. CMS should not assume that the MACs are familiar with the gapfilling regulations or the history of the rulemaking. Over the course of the last year since CMS determined that the molecular pathology codes would be gapfilled, we are aware of several instances where more clear and explicit instructions from CMS to the MACs about the gapfilling process could have prevented confusion and missteps. We hope that in this case, CMS will make clear to the MACs that they may not price molecular pathology tests below the NLA in 2014.

C. Contractors' Processes for Developing Prices

As we have discussed with your colleagues and you in the past, we continue to be disappointed with the lack of transparency in the development of gapfill prices. Without the data on which CMS, Palmetto GBA, and other MACs have based prices, we are unable to evaluate the accuracy and fairness of those prices and to provide CMS with constructive feedback on them. In its regulations and in the process for pricing new laboratory tests, CMS places great emphasis on input and recommendations from the stakeholders. The agency should ensure that laboratories and other stakeholders are able to determine how the final prices have been derived and from what data sources.

In particular, it is critical that we receive more information from Palmetto GBA about how it arrived at its prices. This is because at least three other MACs based their prices on Palmetto's prices, meaning that half of the gapfill prices are Palmetto's prices or are derived from Palmetto's prices. To be fair, ACLA and its members have had some informative communications with Palmetto GBA about its process for arriving at gapfill prices. Palmetto representatives have been willing to meet in person and on teleconferences with members of the laboratory industry to discuss the gapfilling exercise (as well as the MolDx program). However, Palmetto has not provided the laboratory industry with the data it gathered as part of the gapfilling exercise. We have been told that Palmetto started with data "from CMS that was compiled from all of the comments/submissions of individual labs and various associations," but neither ACLA nor its member laboratories have access to CMS's compiled data. Palmetto also told us that, using a consultant (whom it will not name), it obtained "detailed cost data" over the telephone from eight to 10 labs on the direct and indirect costs of a "core set" of lab tests.

Ambulance Inflation Factor Update for CY 2007 71 Fed. Reg. 69624, 69704 (Dec. 1, 2006).

Because we do not know the identity of Palmetto's consultant or the names, positions, and laboratories of the individuals who purportedly provided Palmetto with the cost data, and because we have not received the cost data itself (which Palmetto had agree to share), it is impossible for ACLA and its members to provide meaningful input to CMS on the gapfilled prices.

Moreover, Palmetto repeatedly has insisted that laboratories provide it with data in order to rebut decisions it has made. We do not believe that data sharing should be unidirectional. The gapfilling exercise is designed to be a collaborative process that involves input from stakeholders and the MACs alike, and data should be shared with stakeholders more readily. Currently, there is an information imbalance between the parties that undermines the process.

As a step toward greater transparency in the gapfilling process, we request that CMS and Palmetto release the data they have collected about direct and indirect costs of molecular pathology tests and the sources of that data. Just two months ago, CMS Administrative Marilyn Tavenner penned an article for the *Health Affairs* blog entitled "CMS Progress toward Greater Data Transparency."[11] In the piece, the Administrator says, "Over time it has become very clear that health care today relies on sharing data to drive improvements in access and care delivery as well as control costs," and she states that CMS "has embraced the need for greater data transparency" in many facets of its operations. The gapfilling process should be part of the Administrator's insistence on greater data transparency, and we urge you to take concrete steps to ensure that it is.

D. Conclusion

In summary, we request that CMS price all of the 116 molecular pathology tests that are part of this gapfilling exercise and to remove coverage considerations from the pricing process entirely. CMS also should provide unambiguous instructions to the MACs that they may not reimburse gapfilled tests in 2014 at any price below the NLA. Additionally, we continue to urge CMS to bring a greater measure of transparency to the gapfilling process by making available to laboratories and other stakeholders the data that the agency and the MACs have used to arrive at gapfill prices.

As always, we thank you for your attention to our concerns.

Sincerely,

JoAnne Glisson
Senior Vice President, ACLA

[11] Marilyn Tavenner and Niall Brennan, *CMS Progress Toward Greater Data Transparency*, Health Affairs Blog, July 31, 2013, *available at* http://healthaffairs.org/blog/2013/07/31/cms-progress-towards-greater-data-transparency/.