



July 8, 2013

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850
Filed Electronically: MoPathGapfillInquiries@cms.hhs.gov

RE: Molecular Diagnostics Gapfill Payment Amounts, Clinical Laboratory Fee Schedule

Dear Ms. Tavenner:

On behalf of the Personalized Medicine Coalition (PMC), I am pleased to submit comments on the Centers for Medicare & Medicaid Services (CMS) Gapfill Payment Amounts, Clinical Laboratory Fee Schedule (CLFS).

Personalized medicine is an emerging field of medicine that uses diagnostic tools to identify specific biological markers, often genetic, and help assess which medical treatments and procedures will be best for each patient. By combining this information with the individual's medical history and circumstances, personalized medicine allows doctors and patients to develop cost-saving targeted prevention and treatment plans. Personalized medicine therefore has the potential to optimize delivery and dosing of treatments so patients can receive the most benefit with the least amount of risk, eliminating the difficulties of the trial-and-error process many patients endure to obtain the correct diagnosis and treatment for their condition.

PMC is an education and advocacy organization that promotes the understanding and adoption of personalized medicine to benefit patients and the health care system. We represent more than 225 academic, patient, provider, and payer organizations, as well as drug and diagnostic manufacturers and clinical laboratories. Given the mission and the desires of the patient and health care stakeholder communities we bring together, the PMC has a keen interest in CMS's 2013 CLFS Gapfill Payment Amounts for molecular diagnostic testing.

Overall, PMC members are concerned that insufficient payment amounts threaten the sustainability of the laboratory industry and continued investment in the developing field of personalized medicine, thereby removing the promise of sustaining innovation in health care and possibly lowering overall costs by eliminating unnecessary and or ineffective treatments.

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Specifically, PMC believes that the proposed molecular diagnostic gapfill payment schedule:

- *threatens the future of healthcare by not addressing potential unintended consequences*
- *confuses stakeholders due to the lack of transparency in the gapfill process; and*
- *reduces the quality of patient care and patient access.*

I. PMC is concerned about the unintended consequences of the proposed gapfill payments on the future of personalized medicine.

Personalized medicine is changing how medicine is practiced. Its impact is notably evident in serious and life-threatening conditions that have previously lacked efficacious treatments. Through the use of molecular diagnostics, health care quality is increasing while efficiencies of health care delivery are improving. *However, poorly developed and executed policy decisions, like the gapfill payment process, will negatively impact healthcare quality improvements in three ways, namely:*

- *halting drug-diagnostic company collaborations which, in turn, will impede the development of targeted medicines;*
- *discouraging investment in the life sciences, and*
- *triggering national job loss in the science and technology sector.*

The co-development of a drug product with a companion diagnostic test is still a fairly nascent field filled with uncertainty for many pharmaceutical companies and diagnostic test developers. Among its challenges are the substantial time and resource commitments for the research and development of diagnostic tests linked to therapies but also the delivery of these innovations by providers. The prospect of insufficient reimbursement for tests, perhaps below the costs of diagnostic test development, conduct, and interpretation, will further compound these challenges. PMC fears that companies will be less likely to invest in diagnostic tests even though the tests hold the potential to provide better health care at lower costs. Furthermore, some of our members report that drug and diagnostic companies are having difficulties constructing co-development agreements because the reimbursement considerations for drug and test combinations in clinical practice are unclear.

Another source of support for the development of new diagnostic tests is the venture capital community. Many innovative personalized medicine diagnostics are developed and brought to market by venture-backed small companies. PMC is concerned that venture companies will view policies like CMS's gapfill payment process as an ominous sign for the future of the life sciences sector. Faced with the probability of inadequate return on their investment, they will choose to halt investment in the life sciences, particularly diagnostic tests, which will slow medical progress and new treatment options for patients, a trend that has already begun.

Finally, we are concerned about the consequences for jobs in science and technology. While large laboratories have diverse menus of services, PMC's membership includes labs that focus exclusively on personalized medicine diagnostics. With payments set at markedly lower levels, we fear these labs will go out of business. We are aware of two labs that have already closed their doors due to this issue. This disruption will endanger patients' and their health care providers' access to testing and weaken our nation's diagnostics industry, ultimately hindering the benefits of personalized medicine in health care.

We ask that CMS consider these unintended consequences of gapfill payment decisions and other policies as they work through this issue.

II. PMC is concerned about the level of stakeholder engagement and the lack of transparency in the gapfill process.

Before 2013, molecular diagnostic tests were reimbursed through a process in which payments for multiple Current Procedural Terminology (CPT) codes, each describing a part of the test, were “stacked” to arrive at the final payment for a test. As part of efforts to improve transparency in billing, CMS decided to restructure the process. As a result, new CPT codes were developed to describe over 100 molecular tests, most of which have been in standard clinical use for many years. As a first step to setting payments for these new codes, CMS charged regional Medicare Administrative Contractors (MACs) to set new prices through a process called “gapfilling”. Some MACs have set pricing at about 30% of what the old code stack provided. Yet in many cases no background information or methodology was given to explain how contractors arrived at those prices. Also, some MACs have failed to determine prices for all codes.

PMC is concerned with how the gapfill process unfolded. It is unclear how each contractor determined prices for codes and how many laboratories provided data for local contractors to consider. Also, since some local MACs appear to have adopted prices established by one of the MACs, it is unclear how CMS can properly use non-independent prices to set national prices. Payments should cover the reasonable cost of supplies, test performance, operating a clinical laboratory, and often test interpretation. Many PMC members report that some of the new prices fall well below this critical threshold.

To bring transparency to this process, we suggest that CMS request all MACs disclose pricing methodology and describe the data used to determine their new payment schedule. Furthermore, we ask that this process be revisited and revised to be as transparent as possible. We ask for significant stakeholder engagement, including public meetings, in each step of a new process resulting in payments that are evidence-based, transparent, and reflect reasonable costs associated with molecular diagnostics.

III. PMC is concerned about the impact that inadequate payments will have on patient access to high quality care.

PMC is concerned that inadequate payments are, in essence, a non-coverage decision with the potential to negatively impact treatment decision-making by patients and their health care providers. Coverage decisions should be determined through a separate process and *de facto* non-coverage through payment decisions is not appropriate.

Limiting access to personalized medicine will delay getting the right treatment to the right patient. It will lock in our current one-size-fits-all, trial-and-error system that all stakeholders, including payers, but most importantly patients, would like to move beyond. Identifying the right treatment for the right patient the first time will enable the delivery of high-quality, more efficient, higher-value, care, which is better for patients and better for the health system.

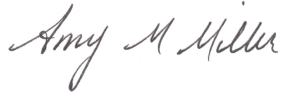
Conclusion

Coverage and payment decisions should be separate processes. When CMS decides to cover a test, we ask that the payment reflect the reasonable cost of performing that test in a high-complexity molecular laboratory by highly trained professionals, as well as covering the associated research and development costs and capital returns required to attract innovators to the industry. Without this support, the future ability of molecular diagnostics to

improve patient care may be compromised and, quite simply, new tests will not be developed and important currently offered tests may be discontinued. Thus patient access to new and improved treatments will suffer.

PMC appreciates the opportunity to provide comments on 2013 Gapfill Payment Amounts. If you have any questions about these comments, please contact me at 202-589-1770, or via electronic mail to amiller@personalizedmedicinecoalition.org.

Sincerely yours,

A handwritten signature in cursive script that reads "Amy M. Miller".

Amy M. Miller, Ph.D.
Vice President, Public Policy