Biotechnology Industry Organization

July 8, 2013

VIA electronic delivery

Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to submit comments on the *Notification of Comment Period –2013 Gapfill Payment Amounts Clinical Laboratory Fee Schedule (CLFS)* published by the Centers for Medicare and Medicaid Services (CMS) on May 9, 2013. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnologies, thereby expanding the boundaries of science to benefit society by providing better healthcare, enhanced agriculture, and a cleaner and safer environment. Specifically, a number of BIO companies develop and market *in vitro* diagnostic technologies for a variety of research, investigational, and clinical uses. In addition, many of BIO's members also develop therapeutic products that are used in coordination with molecular diagnostic tests.

BIO supports patient access to high-quality, innovative diagnostic tests for actionable biomarkers (*i.e.*, tests used to inform clinical decision making). Access to high-quality diagnostic testing is the cornerstone of personalized medicine, ensuring the right patients are treated with the right drug at the right time. Our members are concerned that the recent payment determination

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process for these tests will adversely impact access to these tests. The quality of care for patients with serious conditions will be compromised by impeding the use of molecular diagnostics to help determine the right medicine for the right patient.

Accordingly, BIO members develop both therapeutic and diagnostic products affected by the recent payment determination of the approximately 114 new Molecular Pathology Current Procedural Terminology (CPT) codes (MoPath Codes). BIO is concerned that the proposed gapfilling process resulted in payment levels that are substantially different than those received under the previous "code-stacking" approach to coding. BIO strongly encourages CMS to implement a transparent rate-setting process that incorporates stakeholder input, while also appropriately valuing and supporting innovation. BIO believes the recommendations detailed below are consistent with both the ability of laboratories to provide continued patient access as well as the opportunity for test developers to facilitate innovation in personalized medicine.

I. The Methodology of Rate-Setting for Payment for the MoPath Codes Lacks Transparency and Threatens Access to Personalized Medicine Products and Continued Innovation in this Area

Historically, gap filling is not a frequently used approach for payment determination, and Medicare Administrative Contractors (MACs) are now being mandated to gapfill an unprecedented number of very complicated molecular diagnostic tests. This directive is a considerable new undertaking, and there will be a learning curve associated with the related assessments. Consequently, BIO encourages CMS to provide additional opportunities for stakeholder input. In 2014, CMS will designate national molecular diagnostic test payment amounts based on these previously determined rates. Accommodating feedback from all

interested parties will provide CMS the opportunity to access and utilize the best available information when determining appropriate reimbursement for these tests.

Additionally, BIO is concerned with the lack of transparency and clarity that the proposed gap fill process has for setting molecular diagnostic payment rates. Although BIO appreciates that some MACs are willing to share limited data for certain designated product payment amounts, this information is only communicated to that particular manufacturer or laboratory. Significant lack of clarity remains regarding how MACs will generally disclose their approach to setting payment rates for these products under the new process. This absence of transparency produces uncertainty - both to the accuracy and fairness of the results of this current re-pricing process and also to developers of new molecular diagnostic tests.

It is our understanding that the proposed rate determination approach is based on an average or median of geographically diverse pricing. However, this requirement is undermined by allowing the MACs to share information. Specifically, there are consistencies between the rates that Palmetto GBA assigned these codes and that payment amounts several other MACs have determined for the same codes. BIO urges CMS to clarify how a rate setting process can be fair and reasonable and based on an average when the MACs are setting parallel prices.

In addition, if CMS proceeds with creating a national limit amount (NLA) for the 2014 CLFS, the Agency should set the NLA based on the average of all data received, including from providers, independent labs, and manufacturers. If CMS does follow this direction, then at a minimum, it should set the national limit amount for the 2014 CLFS at the highest MAC interim rate. CMS has authority under the SSA to make adjustments or exceptions for low volume, high cost tests or tests that require specialized personnel. CMS should consider exercising

this authority in order to provide more adequate payment rates for molecular diagnostics.

Regardless of the ultimate approach and final rates produced from this process, CMS should strive for maximum stakeholder input and transparency. To that end, CMS should use data provided by the industry, independent laboratories, and hospital labs. Providing additional opportunities for comment will ensure payment rate setting processes are determined with the best available information. The MACs and CMS must describe generally the methodology used to set the rates, as it is applied to all of the codes.

II. The Lack of Specificity in the MoPath Codes May Lead to Pricing that Is Inadequate to Account for Clinically Relevant Differences among Platforms, and CMS Desire for Increased Evidence on Molecular Diagnostics

BIO is also concerned that a lack of adequate specificity in coding for many of these products may result in an inability to distinguish among important differences in products/services. BIO appreciates that some laboratories or kit manufacturers may furnish a test for an analyte that cost more than other tests for that analyte. Where these tests are comparable in analytical and clinical validity, it is permissible to group them together to come up with median prices to represent the whole. However, the lack of adequate coding specificity for these products results in an inability for CMS to consider and account for differences in quality among these tests or clinically relevant differences among platforms. Consequently, the lines between coverage and payment become blurred. That is, some products that yield potentially higher quality results, or produce a clinically relevant difference due to varied platform or procedure,

could be forced from the market due to payment rates that do not cover the cost of performing the tests, resulting in a *de facto* coverage decision.

If CMS will not provide adequate payment to cover the cost of test administration, patient access is seriously compromised as laboratories will not able to offer the diagnostic to Medicare beneficiaries. In turn, Medicare beneficiaries may experience difficulty accessing these tests, and it is possible that these patients will not receive the appropriate therapies for treating their disease.

The lines between coverage and payment should be clearly demarcated. BIO strongly encourages CMS to appropriately reimburse molecular diagnostic tests in a manner that adequately assesses value and encourages future innovation.

III. CMS Should Create an Appeals Process for Rate Setting for the MoPath Codes That Encourages the Development of Evidence and Rewards Tests that Optimize Care for Medicare Beneficiaries

BIO recognizes the resource limitations that CMS has to devote to rate setting for molecular diagnostics, and also understands CMS desire to use an approach that sets rates based on the target of the test (as reflected in the generic nature of the CPT codes). BIO strongly believes that CMS must take the necessary measures to ensure that the gap-filling process provides adequate and appropriate reimbursement for all molecular diagnostic tests that MACs deem covered. Accordingly, CMS should take the steps described above to ensure that the core of this rate setting process provides adequate and appropriate reimbursement for covered tests. However, BIO suggests that an approach that relies solely on this wholesale methodology runs counter to the ability of test developers to innovate and provide Medicare beneficiaries with high quality tests that best meet the constantly evolving needs of clinicians guiding their

treatment. Accordingly, BIO recommends that CMS create an appeals process that a test developer may choose to employ using a specific code for that particular product or laboratory.

First and importantly, BIO recommends that CMS follow the above comment to ensure transparency in the gap filling for the MoPath Codes. Further, CMS should continue to work with stakeholders to ensure that the payment rates assigned to each CPT code adequately reflect the value these tests provide and support continued innovation

Where a test manufacturer or laboratory believes that this one-size-fits-all approach to rate-setting for each MoPath Code does not reflect the value its test provides for the management and treatment of Medicare beneficiaries, there should be an appeals mechanism that would price the particular test using a product and/or laboratory specific code. Under this approach, developers of tests that use a different platform or produce higher quality results based on increased resources, or involve a platform with some clinically significant difference, could demonstrate these attributes by submitting evidence through the appeals process. This optional appeal process would – in those circumstances where the test manufacturer or test developer is inclined to invest the effort and resources – provide a mechanism for setting payment rates that is not blinded to differences in quality among these tests or clinically relevant differences among platforms. BIO believes that this approach would result in a pathway that is consistent with continued innovation in personalized medicine and CMS' desire for high quality, evidence-supported molecular diagnostic tests.

To implement this approach, BIO recommends that CMS employ in the appeal process a specific coding system, such as the Z codes created by McKesson and Palmetto Test Identifiers (PTI), which are currently used in Palmetto GBA's MolDx program. This system codes products in a test and/or laboratory specific

manner, and is suited to accommodate the specificity required for the approach described above by allowing further granularity on coverage and reimbursement

BIO does not envision this approach as an alternative for fixing the deficiencies in the gap-filling process described above. Rather, this appeals process should be available to test developers as a means to demonstrate a need for product/laboratory-specific payment where warranted by a demonstrated clinical difference in quality or platform.

BIO recommends that CMS implement an appeals process for the MoPath codes that offers the ability to use a product or laboratory specific code to set a rate for reimbursement. BIO suggests using a product/laboratory-specific code system, such as McKesson's Z Code system and Palmetto's PTI to effectuate this appeals process.

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BIO appreciates the opportunity to provide these comments, and would be happy to work with the agency to address any of the concerns raised herein.

Sincerely,

Paul Sheives, JD
Director, Diagnostics and Personalized Medicine Policy