



**ASSOCIATION FOR MOLECULAR PATHOLOGY**  
*Education. Innovation & Improved Patient Care. Advocacy.*  
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January 27, 2014

Administrator Marilyn Tavenner  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue SW  
Washington, DC 20201

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, and Other Revisions to Part B for CY 2014, Final Rule (CMS-1600-FC)

Dear Ms. Tavenner:

The Association for Molecular Pathology (AMP) appreciates the opportunity to comment on the final rule CMS-1600-FC entitled "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014." AMP is an international medical and professional association representing approximately 2,000 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine and the in vitro diagnostics industry.

AMP is providing comments focusing on Payment for Molecular Pathology Services and Policies Regarding Technological Changes.

#### **Molecular Pathology Professional Services**

We note that CMS finalized the interim value for HCPCS code G0452-26. We support that CMS recognizes the need for a mechanism for reimbursing pathologists and other qualified healthcare providers for these professional services provided to Medicare beneficiaries. We alert you to the problem that pathologists are still experiencing difficulty receiving reimbursement from the Medicare Administrative Contractors. We request that CMS to instruct the carriers to provide details to providers explaining why this code is being denied or not being recognized.

#### **Policies Regarding Technological Changes Under Section 1833(h)(2)(A)(i) of the Act a. Background on Technological Changes**

We are concerned about statements in this section regarding costs for point-of-care testing and sequencing genomes and believe they require attention as they may incorrectly influence the proposed process of revaluing the Clinical Laboratory Fee Schedule and future coding and payment determinations.

##### 1) Point-of-care testing

We agree that point-of-care testing, in some instances, "has resulted in smaller and more portable test kits that are simple to use." and provide benefit in certain situations including potentially decreasing aggregate costs of a patient encounter. However, the CMS should understand that because POC testing is performed on a patient-

by-patient basis, the 'per test' costs of point-of-care testing are often higher than those of comparable batched, automated, centralized laboratory testing. Increased costs to the manufacturer related to research and development, clinical testing and regulatory compliance are reflected in the downstream supply costs of point-of-care testing platforms and reagents. These costs may be higher than those for tests performed in the central laboratory. They may offset the higher costs of labor associated with performing the tests in a clinical lab setting. We highlight this issue as we are not aware that CMS has collected data to validate the assumptions made in the Rule that the costs of performing a point-of-care test will be lower than the costs of central laboratory testing. We encourage the CMS to collect such evidence as it considers pricing tests performed on different test platforms.

## 2) Costs of sequencing genomes

CMS states "The cost of sequencing a genome has dropped dramatically since the early inception of this technology in 2001 from more than \$95 million per genome to approximately \$5,700 in early 2013...". Though we acknowledge the inherent truth in that statement regarding the technical challenges in sequencing the human genome, application to patient care requires additional components that must be considered in determining the healthcare cost.

First, costs will vary based on the equipment and assumptions made and the setting for which the sequencing is performed. For example, one vendor recently announced a milestone achievement in technical cost reduction. We would emphasize to the CMS, that in this announcement the only costs included in the vendor's calculation included the high-throughput instrument infrastructure, reagents and amortization of the instrument using ten total instruments and under the assumption that 18,000 human genomes would be sequenced per year.<sup>1</sup>

Second, the costs reported are based on research and development experience. They do not consider costs associated with the clinical setting including quality control and assurance measures required for a CLIA certified laboratory, indirect or overhead costs, and regulated clinical laboratory staff rather than research personnel.

Third, the cost of genomic sequencing does not include the cost of interpreting those sequence results in the context of the clinical findings for the benefit of patient care. This professional work includes the cost of the informatics infrastructure required to generate the appropriate sequence data and the pathologist or other qualified healthcare provider to interpret the finding in the context of the clinical presentation.

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Failure to recognize these additional components, in particular the professional work interpreting rare and private variation in both inherited genetic disease and oncology where the heterogeneity of disease is profound, may lead to undervaluation of these procedures and may cause laboratories to revert to more expensive iterative testing which is reimbursed, leading to higher costs and a detriment to patients and the healthcare system.

The Association for Molecular Pathology appreciates the opportunity to comment and your consideration of our concerns and recommendations. Please direct questions to Mary Williams at [mwilliams@amp.org](mailto:mwilliams@amp.org).

Sincerely,



Elaine Lyon, PhD  
President

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<sup>1</sup> Illumina, Inc. at JPMorgan Healthcare Conference January 14, 2014. San Francisco, CA. Access presentation from <http://investor.illumina.com/phoenix.zhtml?c=121127&p=irol-EventDetails&EventId=5075934> Last accessed January 24, 2014.