

The undersigned organizations represent over 120,000 medical and laboratory professionals and their institutions that perform the vast majority of clinical molecular pathology testing in the United States. Our professionals develop, validate, implement and maintain molecular pathology tests; promote proper test utilization; and provide professional interpretation of test results. Our collective mission is to provide the necessary components of quality laboratory testing, including the application of scientific discoveries in the clinical laboratory, education, certification, accreditation and advocacy on behalf of patients worldwide.

On February 1, 2013, soon after publication by the J10 Medicare Contractor (Cahaba) of its fee schedule for the 78 Tier 1 molecular pathology CPT codes, the J1 Medicare Contractor (Palmetto GBA) published its fee schedule for those codes. Several other contractors published their initial rates for the 78 Tier 1 codes soon thereafter, most adopting Palmetto's rates in whole or in part. The rationale for these fee schedules remains elusive, and importantly these fee schedules have impacted revenue so severely that the continued existence of some laboratories is in jeopardy. We are concerned that these payment decisions may adversely affect clinical decisions, patient access to valuable health care services, and patient outcomes.

Our groups would like to highlight a number of aspects of the preliminary payment policies that need to be considered as CMS moves forward:

- Medicare contractors are denying molecular pathology test claims or significantly reducing payment rates without public justification for these decisions;
- Some contractors are mischaracterizing certain molecular pathology tests (e.g., CPT 81479) as investigational and denying payment;
- Few contractors have engaged the laboratory community to gather needed data or to discuss molecular pathology test pricing;
- Cuts in molecular reimbursement fees may force some testing facilities to stop offering molecular pathology test services, thereby potentially limiting patient access to care and imposing a concomitant negative impact on clinical decision-making; and
- Lower reimbursement for molecular pathology tests may stifle innovation by removing the incentives for developing new tests.

The undersigned organizations respectfully request that CMS actively intervene in this matter by doing the following:

- Ensure reimbursement for molecular pathology tests focus first and foremost on ensuring patients receive the tests they need by minimizing coverage restrictions and payment edits while CMS gains expertise with the new codes;
- Reimburse providers for tests they have already provided since Jan 1, 2013;
- Instruct contractors to make available their data and methodologies to show how they arrived at their pricing determinations, including information about tests they excluded,

and provide the contractors with parameters for how to present their work so that stakeholders have meaningful information to review;

- Provide a transparent payment methodology, so that sources of data are described;
- Extend the reconsideration period through the end of 2013 to allow fine-tuning of payment levels for individual codes; and
- Convene multiple “Open Door Forum” opportunities for the remainder of 2013 to allow dialogue with the laboratory community regarding the price-setting process and to respond to the numerous questions that have arisen and are likely to continue to arise as pricing evolves.

We remain eager to share our expertise with CMS and the Medicare Contractors to provide technical assessments where needed as well as appropriate data to arrive at a fee structure that will help ensure that patients have access to the high quality of personalized care that they so well deserve.

American Association for Clinical Chemistry (AACC)
American Clinical Laboratory Association (ACLA)
American College of Medical Genetics and Genomics (ACMG)
American Society for Clinical Pathology (ASCP)
American Society for Histocompatibility and Immunogenetics (ASHI)
Association for Molecular Pathology (AMP)
California Clinical Laboratory Association (CCLA)
College of American Pathologists (CAP)
Society for Inherited Metabolic Disorders (SIMD)