

November 23, 2015

Delivered by Electronic Mail

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Acting Administrator Slavitt:

We are writing in response to the Centers for Medicare and Medicaid Services (CMS) recently released final payment determinations for drugs of abuse testing under the clinical laboratory fee schedule (CLFS). We recognize that the Agency overhauled the coding and payment rates based on concerns of overutilization; however, the final determinations disproportionately cut payments to reference laboratories specializing in definitive testing. **We are concerned that reference laboratories cannot continue to serve Medicare beneficiaries and their physicians under this payment structure.**

Definitive testing is an essential clinical tool and used as the standard of care to determine whether patients on pain medication are adhering to their drug regimen or whether other non-prescribed medications may be present that pose a risk to Medicare beneficiaries. The final definitive testing rates in many cases are below the fixed costs of performing these tests, including specimen preparation, reagents, allocated instrument capital costs, and testing labor are directly associated with the initial number of tests performed. For example, if six or seven drug tests are performed, then laboratories would receive a fraction of the dollars spent on their testing costs.

Further, the final reimbursement rates for definitive testing represent cuts of more than 50 percent from current levels. This is in stark contrast to Congress' intention in enacting the Protecting Access to Medicare Act (PAMA), which capped reduction rates at ten percent for the first year.

The clinical laboratory community came together to offer reforms and to propose new rates that would represent savings to Medicare and would reflect appropriate reimbursement for drugs of abuse testing. The PAMA advisory panel put forth its own recommendations that more closely aligned with our recommendations. Contrary to those consensus recommendations, CMS went much further in reducing payment rates. As a result, Medicare beneficiaries and their physicians risk losing access to critical tests for drugs of abuse – including areas of the country hardest hit by the epidemic of prescription drug abuse and despite the commitment of President Obama and Secretary Burwell to tackle nationwide prescription drug abuse.



We respectfully request that the Agency reverse this decision. **Specifically, CMS must recalculate the first tier of definitive testing as that is where the bulk of the costs are incurred and use that as the foundation for the tiered pricing structure.** We also would appreciate the opportunity to meet at your earliest convenience to discuss our concerns.

Sincerely,

Coalition for Excellence in Medication Monitoring

On behalf of
Aegis Sciences Corporation
Alere
Ameritox Inc.
Dominion Diagnostics
DRUGSCAN

National Independent Laboratory Association

cc: Sean Cavanaugh, Deputy Administrator and Director, Center for Medicare
Marc Hartstein, Director, Hospital and Ambulatory Policy Group