January 15, 2016

Mr. 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

Re: Reconsideration Request for Final Payment Determination for HCPCS Codes G0480 – G0483, Definitive Drug Testing

Dear Acting Administrator Slavitt:

The National Independent Laboratory Association (NILA) is writing to request reconsideration of the Centers for Medicare and Medicaid Services' (CMS) final payment determinations for HCPCS Codes G0480-G0483 for definitive drug testing. NILA represents over 90 community and regional laboratories, including a significant number of laboratories that specialize in toxicology testing.

Need for Reconsideration

NILA is particularly concerned that the final payment rates issued by CMS for definitive drug testing are below the fixed costs of performing these tests, including specimen preparation, reagents, allocated instrument capital costs, and testing labor. The final reimbursement rates for definitive testing represent a cut of more than 50 percent from current levels. These significant reductions will have a disproportionate effect on small and mid-size laboratories that provide these testing services, as many of these laboratories offer a limited testing menu focused exclusively on toxicology testing. As a result, NILA is extremely concerned about the impact CMS's decision will have on market competition for toxicology testing services.

NILA is alarmed that CMS opted to issue such significant reimbursement reductions at the same time the agency is working to implement Medicare laboratory payment reform as a result of the PAMA statute. That statute requires applicable laboratories to submit their private payor rates, which CMS will then utilize to calculate a weighted median payment rate for each procedure and on Medicare's clinical laboratory fee schedule (CLFS). By reducing definitive drug testing rates under Medicare prior to conducting the PAMA mandated evaluation, CMS has prematurely set a new rate at a level far below the reduction restrictions outlined in the PAMA statute for all tests on the Part B CLFS.

In addition to having a significant, negative impact on competitiveness and test availability within the laboratory market, the decision to drastically cut definitive drug testing reimbursement

prior to the PAMA market evaluation also is in stark contrast to the Administration's expressed goal of addressing the opioid and heroin abuse epidemic in our country. Identifying drug levels through laboratory testing is a significant tool in the effort to curb drug abuse. If the number of laboratories available to perform definitive drug testing dissipates as a result of the major reimbursement cuts imposed by CMS, the government will have tied the hands of doctors who are helping to address this problem.

Definitive Drug Testing

Definitive drug testing is ordered by a physician when it is medically necessary to identify specific medications, illicit substances, and metabolites present in patients who are receiving medical treatment. This type of testing is medically indicated for patients who are receiving chronic opioid therapy and for the diagnosis and treatment of substance use disorders.

NILA members believe that the final pricing determinations made by CMS reflect a fundamental misunderstanding about how and why this testing is performed and the costs associated with this process. Drugs or drug groups require different analytic reagents and instrument setups given variances in the chemical structure of particular drug classes. This often necessitates different sample preparation, which can range from simple to complex, where specimens have to be appropriately adjusted by a trained laboratorian in order to obtain an accurate result. If a physician requests that a specimen be tested for a higher number of drugs, it is likely that additional specimen preparation and expertise is needed by laboratory personnel, and additional runs on equipment are required.

The laboratory community sought to address the complexities and costs involved with definitive drug testing, offering coding options and rate options that reflected fair reimbursement for performing definitive drug testing. The PAMA advisory panel put forth its own recommendations that closely aligned with the laboratory community's recommendations. Contrary to those recommendations, CMS went much further in reducing payment rates.

NILA respectfully requests that the agency reverse its pricing decision. Specifically, CMS should recalculate the first tier of definitive testing where the bulk of the costs are incurred and use that as a foundation for the tiered pricing structure.

In addition, the billing instructions included with the final determination effectively force toxicology laboratories to bill under the first tier for definitive tests by restricting the use of a single "drug class" to once per day. Under the current instructions, for example, a laboratory that is performing definitive testing on one patient sample for opiates (4 drugs), opioids (3 drugs), and oxycodone (1 drug) plus benzodiazepines (5 drugs) and multiple anti-depressants would only receive the $80 reimbursement amount.

We respectfully ask that CMS amend and issue revised billing instructions that will allow laboratories to count the drug classes separately for the AMA CPT® codes that include tiers and to separately bill for NOS codes (80375-80377) and stereoisomer code (80374).

Applying considerable rate reductions to definitive drug testing and subsequently issuing billing instructions that force laboratories to only bill in the lowest price tier, despite the number of drugs tested, provides a double rate reduction on toxicology laboratories that are providing medically necessary drug testing services.

Concurrent Implementation of PAMA

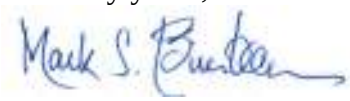
NILA has serious concerns about how the cuts to definitive drug testing will exacerbate the payment reductions toxicology laboratories face as a result of the payment re-pricing scheduled to take effect under PAMA. Private insurers will undoubtedly reevaluate current pricing for drug tests following CMS's Medicare pricing reductions. If laboratories are required to report private payment rates for drug tests under PAMA, two significant problems result: 1) private payer rates will be associated with test codes that do not match the revised Medicare G-codes for tests of the same type, as private payers do not use or typically recognize G-codes; and 2) if such private rates are repriced by payers and are less than the revised Medicare rates, laboratories will be forced to accept additional reductions on top of the cuts CMS made in its final pricing determination, far exceeding the reduction limits outlined in the PAMA statute.

The PAMA statute imposed a ten percent annual limit on the reduction of payments to laboratories over the first three years following the initial market evaluation. Total aggregate cuts to drug testing will drastically exceed this limit with estimated cuts ranging from 50-70 percent over the next couple of years as a result of CMS's pricing decisions taking effect in tandem with PAMA. Such drastic pricing adjustments cannot be absorbed and have a disproportionate effect on small and mid-size laboratory providers.

Conclusion

While we recognize CMS's very real concerns about drug test overutilization, cuts to reimbursement as finalized by the agency will not address this concern. We respectfully request that CMS consider the enormous impact of these policies, and we specifically ask the agency to reconsider the assigned rates for definitive drug testing.

Sincerely yours,



Mark S. Birenbaum, Ph.D., Administrator

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