



October 26, 2015

Delivered by Electronic Mail

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Calendar Year (CY) 2016 Clinical Laboratory Fee Schedule (CLFS) Preliminary Determinations

Dear Acting Administrator Slavitt:

The National Independent Laboratory Association (NILA) welcomes the opportunity to provide comments on Calendar Year (CY) 2016 Clinical Laboratory Fee Schedule (CLFS) Preliminary Determinations, posted on the Centers for Medicare and Medicaid Services (CMS) website on September 25, 2015.

NILA represents independent community and regional laboratories, including toxicology testing laboratories that work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients. Members are community-based businesses that range in size from small to large multi-state regional laboratories. For the majority of NILA's members, 30-50 percent of their testing services are provided to Medicare beneficiaries.

Toxicology testing is performed in laboratories that use advanced technology and skilled toxicologists and other health professionals to ensure accurate and complete test results. NILA is concerned that the rates proposed in the Agency's preliminary determinations for drugs of abuse testing are far below the cost of performing such tests. Implementation of these rates as recommended will effectively diminish competition in the toxicology testing market as community laboratories are unable to afford the cost of providing services. Given the Administration's recent and ongoing attention to the serious opioid abuse epidemic in our country, NILA believes that cutting rates to laboratories that play a vital role in the fight against drug abuse is extremely detrimental to the Administration's goals.

For the below reasons, NILA recommends that CMS not go through with the policy as proposed. Our organization, along with several others in the toxicology testing space, urge CMS to recalculate payment rates that will ensure laboratories can continue to provide testing services and that will not threaten physician access to these important tests. If CMS believes additional dialogue with stakeholders is needed to address the payment calculations, NILA encourages CMS to delay the implementation of the recommended new rates until after Clinical Diagnostic Laboratory Test payment reform takes place in order to gauge rates in comparison to the private market.

The following outlines NILA's key points of disagreement with the CMS recommendations:

- **CMS's recommendation for presumptive testing utilizes current point-of-care testing (POCT) for drugs of abuse as the basis for reducing reimbursement for laboratory-based presumptive testing.** Reimbursement for testing must reflect the complexity of the test and the services provided by laboratories. NILA recommends that CMS not adopt the G-codes as proposed and instead maintain the existing G-codes for presumptive testing.
- **The CMS recommendations for payment rates for definitive drugs of abuse testing are significantly below the cost of providing the tests.** NILA agrees that the appropriate crosswalk for definitive testing is CPT code 82542, but disagrees with how CMS proposes to structure tiers and the use of 0.10 as the multiplier for additional tests in the same tier. The current proposal does not reflect the costs needed to provide these testing services, including the cost of instrumentation and the time of skilled laboratory personnel to adequately review, report, and provide the data to the physician.
- **The CMS proposal to define tiers based on "drug classes" is misguided.** "Drug class" does not have a standard definition, and basing tiers for a new payment structure on this term will create confusion. NILA recommends the use of drugs and their metabolites as the basis for tiers.

Laboratories provide an essential service to physician offices that supports clinical decision-making and enhances patient care. Additionally, laboratory scientists are expert on testing technologies and can provide physicians with guidance in a variety of areas. The relationship between physicians and laboratories is important in medication monitoring, particularly as we continue to understand and fight the growing opioid abuse epidemic across the United States.

NILA strongly advises that CMS reevaluate its proposal, continue to engage with the stakeholder community, consider the negative impact these proposed rates will have on the ability of laboratories to provide needed services, and mitigate the disruption that such a change will cause to the laboratory sector at the beginning of a new Medicare payment reform system.

We appreciate the opportunity to comment on CMS's preliminary recommendations. If you have questions on our comments, please contact NILA's Washington Representative, Julie Allen at Julie.Allen@dbr.com or 202-230-5126.

Sincerely yours,



Mark S. Birenbaum, Ph.D.
Administrator
National Independent Laboratory Association