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House Committee on Ways and Means Pushes Back on PAMA Laboratory Payment Reform Timeline

Washington D.C. – The National Independent Laboratory Association (NILA), representing community and regional independent clinical laboratories across the country, applauds the Chairman and members of the House Ways and Means Committee Subcommittee on Health for raising concern about the implementation of new regulations by the Centers for Medicare and Medicaid Services (CMS) to reform Medicare laboratory test reimbursement. This week a bipartisan majority of the Ways and Means Subcommittee on Health, under the leadership of Subcommittee Chairman Pat Tiberi (R-OH) and committee members Congressman Patrick Meehan (R-PA) and Bill Pascrell (D-NJ) sent a letter to CMS Acting Administrator Andy Slavitt, that strongly advises CMS not to rush the reconfiguration of the Part B Clinical Laboratory Fee Schedule (CLFS) under the Protecting Access to Medicare Act (PAMA) of 2014. The Ways and Means committee members join the chorus of many other House Representatives, the Senate Finance Committee Chairman and Ranking Member, and other Senators who have asked for a delay in the regulations and expressed significant concern with rushing the implementation of a complex payment reform system.

The release of the CMS PAMA regulations on October 1, 2015, came over 17 months after Congress passed the law that requires laboratories on January 1, 2016, to begin reporting all non-capitated privately-contracted insurance rates for every laboratory test they provide and the associated test volumes for each rate. NILA is extremely concerned about the impact this law and corresponding regulations will have on regional and community laboratories and the Medicare beneficiaries they serve. With the release of a late proposed rule and no feedback since comments on the rule closed in November, NILA fears that CMS might rush the finalization of these complex regulations such that NILA members will not have the time or ability to prepare for reporting and to make business adjustments to handle the requirements. At this point, CMS has never pilot tested the new first-time reporting system or provided any understanding of how it will operate.

Under the CMS proposed regulation, reporting requirements would have commenced between January 2016-March 2016. CMS would have then quickly evaluated the anticipated billions of reported data sets to issue new proposed rates by November 2016, issuing new Clinical Laboratory Fee Schedule rates by January 1, 2017 – providing just two months for laboratories to comprehend the impact these adjustments will have on their business and their ability to provide services.

"While NILA has never supported the approach of this law, we want to ensure that a new process for determining Medicare reimbursement rates does not ultimately force smaller laboratories out of

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NILA members are independent community and regional clinical laboratories working with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and home health patients to provide essential clinical laboratory services to Medicare beneficiaries, particularly those in underserved communities and hard-to-reach care settings. Every day, NILA members provide diagnostic laboratory services and results, upon which physicians base their clinical decisions for the Medicare beneficiaries they serve.

Medicare or perhaps out of business altogether—negatively affecting market competition and access to Medicare laboratory services," says Mark Birenbaum, Ph.D., NILA Administrator. "The law itself is fundamentally flawed, as it requires CMS to determine a weighted median of all the test rates/volumes reported in order to set new payment rates. Clearly, the largest players in the laboratory market – the two national publicly-traded laboratories - will drive the test volumes, and their rates will dominate CMS's evaluation. The law does nothing to consider variances in the market and the impact that adjustments will ultimately have on community and regional laboratories, particularly those that offer significantly smaller test menus in comparison to their national competitors."

The laboratory market is derived of independent clinical laboratories – national, regional, and community laboratories, and hospital and physician-owned laboratories. In addition to fast-tracking implementation in the absence of final regulations, the proposed rule seeks to exclude a majority of clinical laboratories, including all hospital and nearly all physician-owned laboratories, from the reporting requirements, which many in the laboratory community believe will inappropriately reduce the new Medicare reimbursement rates.

"The expressed purpose of the law was to establish private market-based rates within Medicare," says Dr. Birenbaum. "How can this be a market assessment, if only one segment of the market is evaluated and that segment is skewed toward the largest players in the market? Add to that CMS's failure to issue regulations and provide the time needed for laboratories to understand requirements, develop brand new reporting systems, test compliance under risk of significant penalties, seek final rate information from payers, or rectify variances in payment amounts, and you have a recipe for disaster. Under these circumstances, laboratory market-based payment reform is fiction at best."

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