

For Immediate Release

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NILA Believes Proposed CMS Regulation Threatens Competition in the Laboratory Market and Access to Laboratory Testing

Washington D.C. – The National Independent Laboratory Association (NILA), representing community and regional clinical laboratories across the country is extremely concerned about implementation of new regulations by the Centers for Medicare and Medicaid Services (CMS) to reform laboratory test pricing.

The release of the CMS regulations on Friday, September 25, 2015, comes over 17 months after Congress passed the *Protecting Access to Medicare Act of 2014*, a 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 with each rate. NILA was already extremely concerned about the impact this law and corresponding regulations would have on regional and community laboratories and the Medicare beneficiaries they serve. Now, NILA is alarmed that CMS would wait and throw complex regulations together in a way that will provide NILA members no time to prepare for reporting or make business adjustments to handle the requirements.

Under the proposed regulation, laboratory reporting would be required between January 2016 and March 2016, though final CMS regulations would not be published until the end of December 2015, at the earliest. CMS would then quickly evaluate the anticipated billions of reported data sets to issue new proposed rates by November 2016, issuing final Clinical Laboratory Fee Schedule rates by January 1, 2017 – providing just two months for laboratories to comprehend the impact adjustments will have on their business and their ability to provide ongoing 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 community and regional laboratories out of 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.”

Upon initial review of the regulation, it is clear that CMS is also focusing the regulation solely on independent laboratories, ignoring the broader laboratory market and the intention of the law.

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“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? From what NILA’s seen so far, the goal is not to modernize a fee schedule; rather, a system is being set up that threatens to make inappropriate adjustments to Medicare rates that benefit the two largest publicly traded laboratories at the expense of community and regional laboratories. This regulation threatens access to laboratory services for Medicare beneficiaries, particularly those living in rural and underserved communities that rely on laboratory tests to guide their care and treatment.”

NILA is closely reviewing the proposed regulation and will issue formal comments on all of the rule’s components.

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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.