



For Immediate Release

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CMS Final Regulation Threatens Access to Laboratory Testing Services for Medicare Beneficiaries

Washington D.C. – The National Independent Laboratory Association (NILA), representing clinical laboratories that serve Medicare and provide services to the most vulnerable beneficiaries is shocked and dismayed by the final regulation released today by the Centers for Medicare and Medicaid Services (CMS) to rewrite payment for clinical laboratory services under Medicare. The regulation fails to address many significant problems highlighted by NILA and shared by members of Congress across the Senate Finance Committee, Energy and Commerce Committee, Ways and Means Committee, and others as noted in numerous letters to the agency over the last year.

When the Protecting Access to Medicare Act (PAMA) became law in April 2014, it required a private market analysis of laboratory payments with the intent of reassessing and repricing laboratory test reimbursement rates under Medicare. Under the final rule, CMS violates the statute, announcing plans to conduct only a limited market assessment, excluding a large percentage of laboratories, including hospital laboratories, and basing its rates off a purposefully skewed data assessment.

While NILA is relieved CMS did not attempt to implement the regulation as originally outlined in its proposed rule, NILA is deeply concerned the agency still plans to begin implementation in less than six months, not providing laboratories sufficient time to develop the information systems necessary to collect, review, and verify data before reporting. According to the final rule, CMS will require laboratories to begin reporting January 1, 2017, all non-capitated privately-contracted insurances rates for every laboratory test they provide and the associated test volumes with each rate. Postponement of implementation was inevitable given CMS's failure to issue a rule in accordance with statute; and allowing only six months before reporting is to begin is not sufficient to ensure laboratories can be compliant.

“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 S. 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

- MORE -

NILA Press Release – CMS Final Regulation Threatens Access to Laboratory Testing Services for Medicare Beneficiaries

June 17, 2016

Page Two

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 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 final regulation and will issue additional information after conducting further analysis.

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NILA members are small community and multi-state regional independent 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.